EXHIBIT 235

Antitrust Law: An Analysis of Antitrust Principles and Their Application - Areeda and Hovenkamp, ¶308. Summary Judgment

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See *United Magazine Co., Inc. v. Curtis Circulation Co*., 279 Fed. Appx. 14, 2008 WL 833077, 2008-1 Trade Cas. ¶76,088 (2d Cir. Mar. 25, 2008, unpublished) (district court properly granted summary judgment on predatory pricing claim that made no sense; publishers allegedly drove distributors out of business through below cost pricing but they could lawfully have simply terminated them).

See *U.S. Information Sys., Inc. v. International Brotherhood of Elec. Workers*, 366 Fed. Appx. 290 (2d Cir. Feb. 19, 2010), cert. denied, 131 S. Ct. 626 (2010) (granting summary judgment on claim that labor union and unionized electrical contractors conspired to exclude firms whose employers were members of a different union; actions were consistent with individual self-interest); *United Magazine Co., Inc. v. Curtis Circulation Co*., 279 Fed. Appx. 14, 2008 WL 833077, 2008-1 Trade Cas. ¶76,088 (2d Cir. Mar. 25, 2008, unpublished) (district court properly granted summary judgment on predatory pricing claim that made no sense; publishers allegedly drove distributors out of business through below cost pricing but they could lawfully have simply terminated them); *Static Random Access Memory Antitrust Litig.,* 2010 WL 5094289, 2011-1 Trade Cas. ¶77,336 (N.D. Cal. Dec. 8, 2010) (accepting expert's analysis of price-fixing transactions to show plaintiff's injury); *ZF Meritor LLC v. Eaton Corp*., 800 F. Supp 2d 633 (D. Del. 2011) (excluding expert testimony that used a reliable procedure for estimating damages but relied on unreliable data); *Grand River Enterps. Six Nations, Ltd. v. King*, 783 F. Supp. 2d 516 (S.D.N.Y. Mar. 17, 2011) (excluding as unreliable expert testimony purporting to infer conspiracy from conscious parallelism); *Hackman v. Dickerson Realtors*, *Inc*., 746 F. Supp. 2d 962 (N.D. Ill. Oct. 23, 2010) (record failed to support claims that realtors conspired to exclude commission-cutter and no individual realtor satisfied power requirements of §2).

308a. The problem; key point..— Summary judgment is particularly important in antitrust cases because of the fearful dimensions that such cases can assume and because of the powerful incentives to offer claims or defenses of little merit. [1] Quite apart from the allure of treble damages, commercial disappointment rather than antitrust policy motivates many claims, while many defenses seek merely to confuse the court, burden plaintiffs, or delay judgment.

Federal Rule of Civil Procedure 56(c) addresses this problem by providing for summary judgment without trial when

> the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law. A summary judgment, interlocutory in character, may be rendered on the issue of liability alone although there is a genuine issue as to the amount of damages.

The Supreme Court emphasized that this language

> mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial. [2]

While a claim or defense need not be supported by probative evidence at the outset, such evidence must be forthcoming once the party seeking summary judgment offers admissible evidence, from persons with personal knowledge of the facts, that there is no genuine issue for trial as to a material fact. [3] Rule 56(e) provides:

> When a motion for summary judgment is made and supported…an adverse party may not rest upon the mere allegations or denials of his pleadings, but his response…must set forth specific facts showing that there is a genuine issue for trial.

Accordingly, the Supreme Court has rejected the contention that antitrust plaintiffs "can get to a jury on the basis of the allegations in their complaints, coupled with the hope that something can be developed at trial" to support the allegations. [4] Thus, once the discovery record has been closed, the party wishing to resist summary judgment must show sufficient dispute about an essential fact and may not offer the argument that, while the fact is not yet in the record, trial may produce it.

Notwithstanding occasional coolness toward summary disposition of antitrust claims, the Court has now made clear that Rule 56 applies to all civil cases in the federal courts. (See ¶¶b - c.) The difficulty, of course, lies in deciding when there is a "genuine issue" that requires trial. Many courts had denied summary judgment when any evidence that was not demonstrably false supported the plaintiff's claim — for example, that evidence of parallel conduct was consistent with the existence of a conspiracy.

However, the Supreme Court has now recognized that if all relevant discovery is in, mere consistency with the allegations or mere dispute between the parties does not necessarily require trial. There is no "genuine issue" as to a material fact unless the record would allow a reasonable jury to find that the claimant has satisfied its proof burden as determined by the governing substantive rule. When the pre-trial record would, were it the trial record, justify a directed verdict, then the Rule 56(c) test is satisfied and that record must be sufficient to allow a reasonable jury to find it more probable than not that such a conspiracy existed. The classic error has been a failure to see that the party bearing the burden of persuading the tribunal that fact *X* exists can prevail only if the reasonable juror can fairly conclude not only that *X* might exist but that *X* is more probable than not. See ¶c.

This process does not turn the judge into a controlling "thirteenth juror." For more than a century judges have exercised a supervisory role at the directed verdict or JNOV stage to determine whether a reasonable jury could find that a key fact was more likely than not to exist. Indeed, the standard for summary judgment is essentially the same as for the later dispositions. The right to a jury trial has always been subject to judicial supervision of this kind. See ¶b, where we also note some obstacles to summary disposition.

The substantive law, of course, defines which issues are material and what proofs are sufficient. For example, a legal doctrine might consider an actor's state of mind, which is often left to the jury, while also requiring proof of market power as an essential element of the plaintiff's case; if the power issue can be decided summarily, that case will be over, no matter what the outcome might have been on the state-of-mind issue. (See ¶d.)

Legal doctrine also bears on summary judgment in a more subtle way. We explain in ¶¶e-i how many apparently factual rulings are really rules of law — for example, about what is needed to establish a conspiracy or the existence of predatory pricing.

We do not undertake any general restatement of the law of summary judgment. [5] Nor is it feasible to preview the details of all substantive antitrust doctrines bearing on the cases discussed in this Paragraph, which relies on cross-references to later chapters. We begin with a few of the reasons impeding summary disposition.

See *Publication Paper Antitrust Litig.*, 690 F.3d 51, 65 (2d Cir. 2012) (record provided sufficient evidence of price-fixing conspiracy; in particular:

> Plaintiffs have provided additional evidence to support a reasonable finding that SENA and UPM engaged in price fixing. The district court found, and defendants do not contest, that the publication paper industry is conducive to collusion: publication paper is a commodity product with few substitutes; the market is controlled by a limited number of sellers (principally, IP, SENA, and UPM); and high capital investment costs limit the entry of new market players. [S1] Furthermore, during the class period, the publication paper industry suffered from excess capacity and historically low prices, conditions that make "price competition more than usually risky and collusion more than usually attractive." Finally, there is ample evidence of conspiratorial behavior. Most notably, it is undisputed that in private phone calls and meetings—for which no social or personal purpose has been persuasively identified— Tynkkynen shared UPM's pricing strategies with Korhonen and both men disclosed to each other their companies' intentions to increase prices before those decisions had been publicly announced. Tynkkynen and Korhonen also developed

a "joint story" to conceal from the government the true nature of their communications—behavior from which a jury could infer that both men were aware that their communications and related actions regarding publication paper pricing violated the law.

See also *Urethane Antitrust Litig.*, 2012 WL 6610878 (D. Kan. Dec. 18, 2012) (The defendant "urges the Court to apply this standard from *Matsushita* by examining every piece of evidence to determine whether it 'tends to exclude the possibility' that the alleged conspirators acted independently. The Supreme Court [in *Matsushita*] was making clear, however, that the evidence, as a whole, must tip the scales…."); *U.S. Info. Sys., Inc. v. International Bhd. of Elec. Workers*, 366 Fed. Appx. 290, 2010 WL 571769, 2010-1 Trade Cas. ¶76,917 (2d Cir. Feb. 19, 2010, unpub.), cert. denied, 131 S. Ct. 626 (2010) (granting summary judgment on claim that labor union and unionized electrical contractors conspired to exclude firms whose employers were members of a different union; actions were consistent with individual self-interest); *United Magazine Co., Inc. v. Curtis Circulation Co.*, 279 Fed. Appx. 14, 2008 WL 833077, 2008-1 Trade Cas. ¶76,088 (2d Cir. Mar. 25, 2008, unpub.) (district court properly granted summary judgment on predatory pricing claim that made no sense; publishers allegedly drove distributors out of business through below cost pricing but they could lawfully have simply terminated them); *ZF Meritor LLC v. Eaton Corp.*, 800 F. Supp. 2d 633 (D. Del. 2011) (excluding expert testimony that used a reliable procedure for estimating damages but relied on unreliable data); *Grand River Enters. Six Nations, Ltd. v. King*, 783 F. Supp. 2d 516 (S.D.N.Y. 2011) (excluding as unreliable expert testimony purporting to infer conspiracy from conscious parallelism); *Hackman v. Dickerson Realtors, Inc.*, 746 F. Supp. 2d 962 (N.D. Ill. 2010) (record failed to support claims that realtors conspired to exclude commission-cutter and no individual realtor satisfied power requirements of §2); *Static Random Access Memory Antitrust Litig.,* 2010 WL 5094289, 2011-1 Trade Cas. ¶77,336 (N.D. Cal. Dec. 8, 2010) (accepting expert's analysis of price-fixing transactions to show plaintiff's injury).

308b. Obstacles to summary judgment..— The first barrier to summary disposition is a psychological one arising from doubt about the nature and content of substantive antitrust offenses. Many judges have not had the opportunity to work their way through this subject, with its often opaque precedents and complex and sometimes meaningless jargon. Judges who doubt their grasp of the subject would rather not decide sharply focused legal questions posed by a motion for summary judgment. Such focused legal issues, which may heighten the opportunity for reversible error, might disappear after some delay. The suit might be dropped or settled or take a different tack in the course of trial, or the surrounding facts actually proved might ease its resolution in one way or another. This psychological barrier can be overcome as the substance of antitrust law becomes better understood.

A second hesitation arises from the fear that early disposition might prematurely save the defendant from the exposure of its wrong. Many of the key facts are peculiarly within the defendant's knowledge. The existence of a conspiracy, for example, may be hidden from the world; knowledge can be expected to replace conjecture only after trial. Similarly, the defendant's motive or intention, which is relevant in some cases, can only be speculated about in advance of discovery or trial. Indeed, the Supreme Court took pains to disapprove summary judgment resting on the plaintiff's apparent inability to satisfy a market-power requirement because discovery had been prematurely circumscribed. [6] Any such concern, however, must disappear once discovery discloses the relevant facts.

A third possible hesitation about granting summary judgment might be doubt that statements and affidavits, interrogatories, and depositions would survive cross-examination at trial. It is often objected, for example, that factual disputes should be resolved at trial. However, two factors moderate the force of this troublesome point. Each party can depose and cross-examine the other side prior to trial and prior to the filing of a summary judgment motion. [7] Furthermore, discovery can be used by either party to buttress its position or to weaken the other's. In the absence of such evidence, the mere disbelief by one party of another's testimony is not usually sufficient ground for rejecting it.

Fourth, some judges have hesitated to deprive the plaintiff of access to the jury, fearing that summary judgment makes the judge a dispositive thirteenth juror. [8] However, judges have always supervised juries, directing or

upsetting verdicts whenever the judges have concluded a reasonable jury could decide only one way. The same standard governs summary judgment. This is not to say that judges should substitute their fact finding for that of the jury or else juries would be superfluous. However, the judge can resolve all reasonable inferences in favor of the party opposing summary judgment, [9] leave ample room for different views of the facts, and yet conclude that no reasonable juror could find more likely than not a fact that is essential to the nonmoving party's case and as to which that party bears the burden of persuasion. As we shall see in ¶¶e-i, moreover, many seeming factual questions turn out to be issues of law that are resolved by strong or weak presumptions.

The fifth obstacle to summary judgment was the Supreme Court's *Poller* language that summary judgment "should be used sparingly" in antitrust cases. [10] As we now show, however, that language had a limited context, as the Court has subsequently ruled.

308c. No "genuine issue" though facts disputed — major Supreme Court holdings; more and less plausible claims..—

1. *Earlier decisions*..— In retrospect, it is hard to extract a serious antitrust issue from the *Poller* case. [11] The actors in Milwaukee were plaintiff UHF television station, *A*, a second UHF station, *B*, owned by Bartell, a more desirable VHF station, *C*, the CBS network, and its station-buying broker, Holt. When CBS, via Holt, acquired *B*, it ended its six-month affiliation with *A*, which then sold its facilities to *B* in return for the latter's facilities and cash, and exited from the market after a few months. Upon affiliating with *C*, CBS ended its *B* operation. The Supreme Court disapproved summary judgment, seeing allegations that CBS had acted with Holt and Bartell and alone (1) to depress the value of *A*'s assets in order to acquire them cheaply and (2) to force out a UHF leader in order to protect CBS's VHF interests.

Although full discovery revealed no such purpose, [12] the majority declared,

> We believe that summary procedures should be used sparingly in complex antitrust litigation where motive and intent play leading roles, the proof is largely in the hands of the alleged conspirators, and hostile witnesses thicken the plot. It is only when the witnesses are present and subject to cross-examination that their credibility and the weight to be given their testimony can be appraised. [13]

In fact, nothing in Rule 56 provides or even implies that summary judgment is less appropriate in antitrust cases than elsewhere. Nor did the quoted statement address antitrust cases generally; it spoke only of those antitrust cases turning on motive and intent, the testimony of hostile witnesses, and witness credibility. Once the Court decided, whether correctly or not, that intent and credibility were critical, summary judgment was indeed inappropriate. [14]

The Supreme Court also rejected summary judgment in *Norfolk Monument*. [15] The essential fact was that the plaintiff's sales of grave markers were impaired when nearby cemeteries specified the alloy content of certain markers, charged substantial installation fees on markers purchased elsewhere, and otherwise discouraged customers from buying "outside" markers. Many of these practices were suggested by a rival firm that sold markers to some of the defendant cemeteries (and that evaded or violated outstanding consent decrees). The practices and charges of the several cemeteries were not identical, and some varied substantially. While installation charges seemed extravagant, each cemetery could be understood to exploit its position as land owner to discourage or exclude outside suppliers. Apart from partial parallelism among the cemeteries, there was no evidence of a horizontal agreement among them or even of a vertical agreement with the rival manufacturer. [16] But parallel action does not satisfy even the most expansive conceptions of conspiracy unless the conduct is interdependent. Unless cemeteries were in competition with each other and consumers had a significant brand preference for plaintiff's grave markers, each cemetery would not care whether another cemetery charged a low or an exorbitant installation fee for markers purchased from persons other than the cemeteries. Absent some reason for believing that such interdependence existed, each cemetery's behavior can be explained as an independently-arrived-at and non-interdependent decision to further its own profits. That

the rival supplier pointed out these opportunities for profit to the cemeteries would not indicate any agreement among them. [17] In any event, "conspiracy" as ordinarily defined does not include mere parallel, interdependent, supracompetitive prices. [18]

In disapproving summary judgment in *Norfolk*, the Supreme Court held that

> the alleged conspiracy had not been conclusively disproved by pretrial discovery and there remained material issues of fact which could only be resolved by the jury after a plenary trial. [19]

The Court did not mean that plaintiffs always get to the jury until their allegations are "conclusively disproved." Rather, the Court saw sufficient evidence of conspiracy that had not been adequately rebutted.

This reading makes *Norfolk* consistent with later Supreme Court rulings. In *First National Bank*, the Court cited *Poller* for its point that "given no contrary evidence, a jury question might well be presented as to [defendant's] motives in not dealing with [plaintiff]….However…the record in this case [*First National*] contains an overwhelming amount of such contrary evidence…." [20] Thus, the Court did not insist that the defendant conclusively disprove its alleged participation in a conspiracy. It was enough that the evidence prevented a reasonable jury from finding that the plaintiff had met its burden of proving that the alleged conspiracy was more likely than not. [21]

308c2. *Matsushita..*— In its *Matsushita* decision the Supreme Court clarified many issues left unaddressed or unresolved by the earlier decisions. [22] More significantly, it changed what courts had previously seen, perhaps incorrectly, as a presumption against the granting of summary judgment in complex antitrust cases. Any such presumption has now disappeared. [23]

The plaintiffs, domestic television manufacturers, alleged that their Japanese competitors agreed with one another to fix the price of television sets high in Japan and predatorily low in the United States. High prices in Japan did not injure the domestic manufacturers, [24] and extensive discovery revealed virtually no evidence of any price-fixing agreement by the Japanese manufacturers in the United States. Summary judgment for the defendants was reversed by the Third Circuit, which was reversed in turn by the Supreme Court.

The Court ruled that "a genuine issue of material fact" is not established by

> some metaphysical doubt as to the material facts….Where the record taken as a whole could not lead a rational trier of fact to find for the non-moving party, there is no "genuine issue for trial." [25]

The alleged conspiracy did not seem more likely than not when the alleged predatory campaign had allegedly continued for some 20 years — too long a period to make its ultimate profitability plausible; [26] the defendants lacked a dominant market share; [27] and they numbered 21 — too many to achieve monopolistic tacit price coordination later. In short, successful predation seemed implausible, and

> if the factual context renders respondents' claim implausible — if the claim is one that simply makes no economic sense — respondents must come forward with more persuasive evidence to support their claim than would otherwise be necessary. [28]

While facts and inferences "must be viewed in the light most favorable" to the plaintiffs,

> antitrust law limits the range of permissible inferences from ambiguous evidence in a §1 case. Thus, in *Monsanto* [29] …we held that conduct as consistent with permissible competition as with illegal conspiracy does not, standing alone, support an inference of antitrust conspiracy….[A] plaintiff seeking damages for a violation of §1 must present evidence "that tends to exclude the possibility" that the alleged conspirators acted independently. Respondents in this case, in other words, must show that the inference of conspiracy is reasonable in light of the competing inferences of independent action…. [30]

The *Monsanto* language quoted in *Matsushita* means that summary judgment should be granted for the defendant unless the evidence as a whole would allow a reasonable fact finder to conclude not just that the evidence is consistent with a conspiracy but that the alleged conspiracy is more probable than not. [31] This interpretation of *Matsushita* is reinforced by the Court's faulting of the Third Circuit for failing to "consider whether it was as plausible to conclude that petitioner's price-cutting behavior was independent and not conspiratorial" as to conclude that it was conspiratorial. [32]

Matsushita thus emphasized a party's burden of proof: when the evidence is in equipoise on a matter that a party must establish by a preponderance of the evidence, summary judgment will be granted against that party. Interestingly, the dissenting Justices accused the majority of weighing the evidence [33] without acknowledging that judges always "weigh" evidence in the sense of determining whether a reasonable jury could find conspiracy more likely than not. The question is not, as the Third Circuit once said, whether the plaintiff's inferences are "so far-fetched that a trier of fact should not be allowed to consider them, [34] but whether the evidence, though not far-fetched, sufficed to met the plaintiff's burden of proof.

Quite wrong, therefore, was the Ninth Circuit panel that denied that *Matsushita*'s "more likely than not" language meant

> that a district court may grant summary judgment to antitrust defendants whenever the court concludes that inferences of conspiracy and inferences of innocent conduct are equally plausible. [35]

That was exactly what *Matsushita* held: equal plausibility means that neither interpretation is more likely than not and thus that the party with the burden of persuasion has not satisfied it. More than consistency is required in order to tilt the inference from independent to concerted action. That is what the Supreme Court meant when it required evidence tending to exclude the possibility of independent behavior.

The Ninth Circuit feared that

> requiring judges to ask whether the circumstantial evidence is more "consistent" with the defendants' theory than with the plaintiff's theory would imply that the jury should be permitted to choose an inference of conspiracy only if the judge has first decided that he would himself draw that inference. [36]

But assessing the sufficiency of the evidence to determine whether a reasonable juror could find that the plaintiff has satisfied its burden of persuasion is a traditional judicial function in deciding whether a defendant is entitled to a directed verdict or JNOV. This role has never been thought to make the judge a thirteenth juror or to depend on what the judge would decide, were he or she a juror. The same is true at the summary judgment stage. *Matsushita* tells us that if the post-discovery evidence were the evidence at trial and if a party (whether plaintiff or defendant) is entitled to a directed verdict on such a record, then that party is entitled to summary judgment before trial.

In its *Brooke* decision, moreover, the Supreme Court applied the same standard to approve judgment for the defendant notwithstanding a jury verdict for the plaintiff after a long trial. [37] The Court cited summary judgment cases without differentiating JNOV [38] and explained that "summary disposition of the case is appropriate" when market structure — concentration, easy entry, or insufficient capacity to depress market prices predatorily — shows that predation would not pay off for the predator. [39] A majority of the Justices concluded that no reasonable jury could find that potential recoupment — an essential element to sustain a predatory pricing finding [40] — was more likely than not.

Most of the lower courts have understood the *Matsushita* message. For example, a court that considered predatory intent an essential element of a predatory pricing claim gave the defendant summary judgment because the evidence was in equipoise — "as consistent with permissible competitive motivation as with noncompetitive motivation" — and thus insufficient to satisfy the plaintiff's proof burden by excluding "a

reasonable inference that the defendant was engaged in permissible competition." [41] Courts often say that a party cannot resist summary judgment with evidence that is merely "ambiguous" in the sense that it is "as consistent with" conspiracy as with unilateral conduct. [42] With that kind of ambiguity, a reasonable jury could not say that conspiracy is more likely than not. [43] Mere circumstantial evidence of conspiracy may not defeat summary judgment unless that evidence would allow an inference that conspiracy is more probable than an inference of independent action. [44]

We now illustrate the central proposition that the key to summary judgment is careful definition of the elements of substantive doctrine and the presumptions that guide their application.

308c3. *More and less plausible claims..*— *Matsushita*spoke in the context of an alleged highly implausible decades-long predatory pricing conspiracy and found a severe proof requirement in such cases. Accordingly, when the claim is more plausible, less proof is required to avoid summary judgment.

In the *HFCS* litigation the Seventh Circuit observed about *Matsushita*: [45]

> More evidence is required the less plausible the charge of collusive conduct. In *Matsushita*, for example, the charge was that the defendants had conspired to lower prices below cost in order to drive out competitors, and then to raise prices to monopoly levels. This was implausible for a variety of reasons, such as that it would mean that losses would be incurred in the near term in exchange for the speculative possibility of more than making them up in the uncertain and perhaps remote future — when, moreover, the competitors might come right back into the market as soon as (or shortly after) prices rose above cost, thus thwarting the conspirators' effort at recouping their losses with a commensurate profit. But the charge in this case involves no implausibility. The charge is of a garden-variety price-fixing conspiracy orchestrated by a firm, ADM, conceded to have fixed prices on related products (lysine and citric acid) during a period overlapping the period of the alleged conspiracy to fix the prices of HFCS. [46]

The court then noted that the trial judge had granted summary judgment because the evidence would not establish that a conspiracy existed unless the fact finder drew a "substantial inference." The Seventh Circuit replied:

> This is correct in the sense that no single piece of evidence that we're about to summarize is sufficient in itself to prove a price-fixing conspiracy. But that is not the question. The question is simply whether this evidence, considered as a whole and in combination with the economic evidence, is sufficient to defeat summary judgment. The judge may have been confused by the language found in cases such as In re Baby Food Antitrust Litigation, 166 F.3d 112, 118 (3d Cir. 1999), that "direct evidence in a Section 1 conspiracy must be evidence that is explicit and requires no inferences to establish the proposition or conclusion being asserted." We tried in Troupe v. May Department Stores Co., 20 F.3d 734, 736-37 (7th Cir. 1994), to straighten out the confusing (and, as it seems to us, largely if not entirely superfluous) distinction between direct and circumstantial evidence. The former is evidence tantamount to an acknowledgment of guilt; the latter is everything else including ambiguous statements. These are not to be disregarded because of their ambiguity; most cases are constructed out of a tissue of such statements and other circumstantial evidence, since an outright confession will ordinarily obviate the need for a trial. [47]

In sum, in a case in which conspiracy is deemed quite plausible, perhaps by virtue of the industry's structure and past attempts at collusion, then a broader range of inferences can be drawn from ambiguous evidence.

308d. Single issue can resolve or simplify case..— To point out the obvious, summary judgment can be appropriate on one factual dispute in a case even though one or more "genuine issues" remain. Early resolution of one issue can simplify the subsequent trial or even eliminate the occasion for any trial, for the court must dismiss the plaintiff who cannot produce sufficient evidence of an element essential to its claim. [48]

In *Brooke*, for example, the Supreme Court held that predatory pricing requires proof of below-cost pricing

with actual (or reasonably likely) recoupment of predatory losses through later monopolistic prices. [49] Once the Court concluded that no reasonable jury could find recoupment, it approved judgment for the defendant notwithstanding the verdict against it; and notwithstanding adequate proof of below-cost pricing, predatory intent, and other issues.

308e. Exception to per se condemnation..— Many summary judgment controversies turn on matters of legal doctrine rather than on the facts. In the *Palmer* case, for example, prices nearly tripled after a local and national seller of Georgia bar review courses expressly agreed that the national firm would sell its Georgia materials through the local firm, which agreed not to compete with the national firm in any other state. [50] Notwithstanding this explicit agreement dividing territories between competitors, the Eleventh Circuit approved summary judgment for defendants on the ground that the local firm would not have operated outside of Georgia in any event, and therefore its conduct was consistent with permissible competition and thus could not "support an inference of antitrust conspiracy," especially when the price rise was as consistent with increased costs as with gouging consumers. [51] The court was entirely wrong. Doubt that prices were supracompetitive may prevent inferring an agreement from ambiguous evidence but does not excuse an express agreement of the kind usually condemned per se. [52] The Supreme Court reversed per curiam and adopted the legal rule that an intention to remain within one's own market does not save an express territorial allocation agreement among former competitors. [53]

Similarly, the Supreme Court rejected the legal rule underlying the trial court's grant of summary judgment for the defendant in *Kodak*. [54] While competing in making and selling certain photocopiers, Kodak usually sold unique "aftermarket" repair parts only in connection with its servicing of those machines. Independent firms providing repair services claimed a per se illegal tie of repair parts and service. Because "power" in the tying market was essential to that claim, [55] Kodak obtained summary judgment on the ground that a firm lacking power in the machine market could not have power in the aftermarket, because supracompetitive parts prices could not be sustained without diverting too many machine sales to other manufacturers. Without denying that Kodak's theory might generally be correct, the Supreme Court saw enough evidence in a limited summary judgment record that indicated supracompetitive prices for Kodak parts: it charged more for service than the independents who were preferred by some machine owners and, in effect, charged higher aftermarket prices to those customers who were least likely to consider future repair prices when initially buying the machines. Obviously, and correctly, the Court refused to read *Matsushita* to award summary judgment to one who "enunciates any economic theory supporting its behavior, regardless of its accuracy in reflecting the actual market." [56] Here, the plaintiff's inferences from the summary judgment record seemed reasonable to the Court, which was all that *Matsushita* required; Kodak had not yet shown "that despite evidence of increased prices and excluded competition, an inference of market power is unreasonable." [57]

Mainly, *Kodak* warns that summary judgment should not be granted when further discovery seems helpful to opposing the motion. The trial court had issued summary judgment after severely truncated discovery. In such a case further discovery might establish the defendant's entitlement to summary judgment.

308f. Conduct desirable or not..— The Ninth Circuit has held that equal consistency with innocence did not warrant summary judgment for the defendant unless "an inference of conspiracy would pose a significant deterrent to beneficial procompetitive behavior." [58] True, *Matsushita* had expressed concern that finding a low-priced predatory conspiracy too readily would chill desirable price competition. [59] Moreover, the *Kodak* Court noted in passing that the alleged tie-in did not so "enhance competition" as "to warrant a legal presumption" of non-power "without any evidence of its actual economic impact….[W]hen we weigh the risk of deterring procompetitive behavior by proceeding to trial against the risk that illegal behavior go unpunished, the balance tips against summary judgment." [60]

Contrary to the Ninth Circuit, however, *Matsushita* (or *Kodak*) does not authorize a jury verdict against practices that are not deemed procompetitive without proof that each essential element of the alleged antitrust violation is more likely than not to exist. Plainly, the jury's role is *not* to decide not whether finding a price-fixing conspiracy or market power would harm or benefit society but whether the alleged conspiracy or power exists under the legal definitions provided by the judge. Our quarrel with the Ninth Circuit is therefore that the jury was invited to decide the policy question as well as the fact question.

To be sure, the court's judgment about the utility of conduct bears on the court's formulation of the governing substantive doctrine. In *Monsanto*, for example, the Supreme Court declared that juries may not infer that a manufacturer ceasing to supply one dealer conspired with other dealers merely from evidence that the latter complained about the former. [61] The Court did not deny that such complaints could be connected with the manufacturer's conduct or could bear on whether there was a “meeting of minds” with the complainers. Rather, the Court believed it unfair to tag a manufacturer with conspiracy on the basis of complaints that the manufacturer cannot control, and inefficient to discourage dealers from providing information to their suppliers. The Justices therefore would approve, on policy grounds, summary judgment for a manufacturer when the only evidence of a required conspiracy was conduct consistent with that favored by complaining dealers. The Court did not say that a jury should make that policy decision. Likewise, in *Brooke*, [62] the policy of the antitrust laws to encourage low prices coupled with our sense that predatory pricing rarely occurs serves to require strong elements of proof. This affects summary judgment in the sense that the plaintiff must come in with more and a greater variety of evidence in order to avoid summary judgment. But the policy conclusions are drawn in the formulation of the substantive rules, not in the articulation of summary judgment standards.

That lesson seems to have been overlooked by the Third Circuit, which rejected summary judgment against a claim that a manufacturer conspired with existing dealers to deny a dealership to the plaintiff. [63] Most of allegations or evidence cited by the court merely reiterated that the defendant refused to appoint a new dealer [64] or that existing dealers had told the manufacturer of their opposition to plaintiff. [65] Relying on the latter communications seems inconsistent with *Monsanto*, for listening to the objections of other dealers may serve or disserve the manufacturer's own interest, but the former is much more likely. Finally, the court gave weight to the generality that manufacturers would ordinarily welcome a high-volume, low-price dealer such as the plaintiff. It was equally plausible, of course, that a low-priced plaintiff would free-ride on the sales efforts of other dealers [66] and that his past “sellathon” promotions would undercut the luxury image projected by the defendant's product. [67] Further, for each existing dealer to object to the creation of a new dealership hardly indicated a conspiracy among the existing dealers. Such an objection would be fully consistent with the independent best interest of each. Presumably, each existing dealer would itself sell more vehicles if the plaintiff's dealership were not created. The dissenting judge insisted that summary judgment cannot be avoided simply by showing that the evidence is consistent with an agreement.

Indeed, in a similar case, the Eighth Circuit approved judgment as a matter of law for the manufacturer. [68] The plaintiff dealer sold cars at $49 above invoice — cars that were often taken to other dealers for warranty service, which dealers regard as inadequately compensated. After several dealers complained, GM restricted the plaintiff's purchases. The court understood the complainers' and GM's concern about free riding and thought the evidence, at most, equally consistent with conspiracy as with a unilateral decision by GM.

A related illustration is replacement of one sole-outlet dealer with another. The disappointed dealer then brings an antitrust suit alleging that the manufacturer and substitute dealer conspired unlawfully or monopolized or attempted to monopolize something. [69] The conspiracy claim is usually rejected either because the sole distributorship reflects the manufacturer's unilateral decision rather than any agreement with the new dealer, or because promising a new dealer exclusivity is presumably reasonable. [70] While many such cases are decided summarily, a few courts refuse because of a theoretical possibility that “monopolization” might occur. [71] However, antitrust experience suggests that sole outlets arrangements are virtually always reasonable

when the manufacturer is a competitor and usually when it is a monopolist. Hence, summary judgment should be automatic once the court sees significant competition with the manufacturer. Summary judgment is usually warranted in the rare monopoly case as well, unless the plaintiff has a plausible, factually supported theory under which the termination increases or extends the manufacturer's market power.

In *Ezzo's* the Sixth Circuit found sufficient evidence to preclude summary judgment against a conspiracy claim. [72] The alleged conspiracy was mainly vertical, involving a manufacturer and distributor of beauty products as well as a salon-retailer in competition with the plaintiff. The court noted *Matsushita*'s language that in order "to survive a motion for summary judgment…a plaintiff seeking damages for a violation of [the Sherman Act] §1 must present evidence that tends to exclude the possibility that the alleged conspirators acted independently." [73] However, it was then willing to accept evidence that did "not preclude an inference that Royal and Matrix agreed…." [74] While this standard seems to conflict with the standard that *Matsushita* articulated, the court also noted that:

> *Matsushita*…involved an alleged conspiracy to reduce prices which the Court deemed implausible. This case involves, instead, the classic antitrust situation: an attempt to avoid a competitive marketplace by setting prices at an artificially high level. There is nothing implausible or unlikely about the conduct alleged…in this case. [75]

However, the facts instead suggested that the plaintiff was in violation of the manufacturer's policy of distributing its products only through retailers whose greater business came from styling hair rather than selling products, and that rival dealers had complained about the plaintiff's practices. At that point it would have been in the manufacturer/distributor's best interest to enforce its policy, which would not constitute an agreement with the complaining dealers if the policy furthered the manufacturer's own independent interests.

With respect to claimed horizontal conspiracies, the courts routinely reject at the summary judgment stage allegations that parallel conduct by competitors allows a jury to find that they conspired with each other. [76] This approach results partly from judicial recognition that competitors often respond similarly to common market forces and partly from judicial reluctance to interfere with legitimate business conduct — again, matters of antitrust policy. So, it is often said that a defendant showing "a plausible and justifiable reason for its conduct that is consistent with proper business practice" is entitled to summary judgment on a conspiracy allegation unless the plaintiff provides "specific factual support…tending to show that the defendant was not acting independently" and "from which a jury could reasonably infer that the conduct was conspiratorial." [77]

Of course, conspiracy may be inferred from parallel conduct that deviates from normal business practice or cannot be explained except by conspiracy. [78] For example, in *Petruzzi's*, buyers of meat wastes allegedly conspired to depress buying prices: they did not bid against each other for existing suppliers, who received less than new suppliers, for whom the buyers did bid. [79] They bid up prices offered suppliers by non-cartel buyers. There were also documents suggesting "understandings" among the defendants. The court saw that a buying cartel was plausible. As the court explained in finding evidence of a horizontal conspiracy among buyers sufficient to withstand a summary judgment motion, the two "important circumstances" underlying *Matsushita* were:

> (1) that the plaintiffs' theory of conspiracy was implausible and (2) that permitting an inference of antitrust conspiracy in the circumstances "would have the effect of deterring significant procompetitive conduct." [80] In particular, the *Matsushita* Court worried that if it allowed mistaken inferences to be drawn from the defendants' price cutting policies, it would chill procompetitive behavior. Thus, the Court stated that the acceptable inferences which can be drawn from circumstantial evidence vary with the plausibility of the plaintiffs' theory and the dangers associated with such inferences.

But in the present case,

> in stark contrast with the circumstances in *Matsushita*, the plaintiff's theory of conspiracy is not implausible. In fact, it makes perfect economic sense. In particular, if Petruzzi's IGA is correct, the defendants' action would enable them to make profits that the free market would not allow them, in both the short-run and the long-run. [81]

The court then explained how the defendants were in a perfect situation for profitable buyers' collusion: a concentrated market, a fungible product, inelastic demand, and small sellers who lacked significant power themselves. [82] Further, while predatory pricing threats like the one in *Matsushita* always risk chilling procompetitive behavior, no comparable policy reasons justified reluctance about going after a naked price fixing conspiracy among buyers.

The *Petruzzi* opinion also characterized *Matsushita* as stating that

> in the absence of a plausible theory of conspiracy, a court must consider whether the plaintiff put forward "sufficiently unambiguous" evidence that the defendants conspired. [83] Therefore, in section 1 cases, it is unnecessary for a court to engage in the exercise of distinguishing strong circumstantial evidence of concerted action from direct evidence of concerted action for both are "sufficiently unambiguous." Moreover, in this case, such an exercise is doubly unnecessary because [the plaintiff's] theory is not implausible. [84]

The court later concluded that, while mere consciously parallel behavior alone is insufficient to prove a conspiracy, it does provide circumstantial evidence that, when supplemented by additional evidence, supports an inference of illegal agreement. [85]

The court did not cite *Matsushita*'s footnote 21, which states:

> We do not imply that, if petitioners had had a plausible reason to conspire, ambiguous conduct could suffice to create a triable issue of conspiracy. Our decision in *Monsanto Co. v. Spray-Rite Service Corp.*, 465 U.S. 752 (1984) establishes that conduct that is as consistent with permissible competition as with illegal conspiracy does not, without more, support even an inference of conspiracy. [86]

But the Court surely did not mean by this statement that any evidence insufficient to create a fact issue respecting an "irrational" conspiracy would also fail with respect to a "rational" conspiracy. To the contrary, a large part of the *Matsushita* opinion is taken up with the fact that the conspiracy alleged in that case seemed fundamentally irrational and that a record needs stronger evidence in order to avoid summary judgment when the alleged conspiracy seems economically implausible. For example, *Matsushita* noted that:

> the absence of any plausible motive to engage in the conduct charged is highly relevant to whether a "genuine issue for trial" exists within the meaning of Rule 56(e). Lack of motive bears on the range of permissible conclusions that might be drawn from ambiguous evidence: if petitioners had no rational economic motive to conspire, and if their conduct is consistent with other, equally plausible explanations, the conduct does not give rise to an inference of conspiracy. [87]

Thus the Court's footnote 21 indicated only that there is a minimum evidentiary standard even in cases where the alleged conspiracy is a rational one: if the proffered evidence is equally consistent with competition and collusion, then no fact issue of collusion is established. [88] Footnote 21 should not be read, however, to suggest that given evidence must be treated precisely the same way in all cases. On the contrary, as the Court stated, the "range of permissible conclusions" that a fact finder might draw becomes larger as the alleged conspiracy becomes more economically plausible.

Thus, determining whether a fact issue of conspiracy exists is an exercise in judgment and cannot ignore the overall picture. As previously noted, *Matsushita* alleged a predatory pricing scheme involving as much as 20 years of losses before any prospect of monopoly gains. The substantive law of predatory pricing generally presumes that a rational firm would not engage in such a venture, particularly not when it requires coordinated

pricing by numerous firms. [89] As a result, only the most compelling evidence of conspiracy should suffice to create a fact issue. By contrast, collusion in a concentrated market conducive to price fixing is quite plausible. Further, the behavioral expectations in such markets are that firms will not engage in extensive discussions about prices, urge one another to stop discounting or to stick to list prices, retaliate against price cutters, and the like. Where the underlying conspiracy is itself rational, such evidence goes much further toward establishing a fact issue.

A different problem arises in a market sufficiently concentrated to allow its inhabitants — so-called oligopolists — to coordinate their prices at supracompetitive levels simply by observing one another's conduct in the marketplace. [90] Whether “conspiracy” should be defined to include such oligopolistic coordination is, of course, a legal — not a factual — question that has generally been answered in the negative. [91] To be sure, when competitors provide each other with nonpublic information about their prices or plans, they have “conspired” to that extent, and such a conspiracy can be held unreasonable and condemned if it unjustifiably helps oligopolists coordinate their prices tacitly. [92] But suppose that each competitor merely takes pains to announce its own price increases immediately, loudly, and publicly; the sooner rivals hear, the sooner they will decide whether to follow and the shorter the period at which the price leader is at risk — thus making upward price leadership less dangerous. Such announcements are thus a unilateral (at least) facilitating practice. A Ninth Circuit panel even held that such announcements were unnecessary to communicate with customers in a particular situation and therefore were “not substantially procompetitive.” [93] The court then held that the jury could infer that the announcements were conspiratorial and, in turn, that the defendants had agreed to fix prices.

That court thus made a new rule of antitrust doctrine in the guise of ruling on the factual inferences reasonably available to the jury. The court's new substantive test of conspiracy holds that a jury may (but, apparently, need not) infer a price-fixing conspiracy when the defendants engage in individual but parallel conduct that is not itself significantly procompetitive and that can facilitate oligopolistic coordination. Such a rule, however, does not involve any factual inference of conspiracy. Under the court's logic, condemnation follows once conduct is determined to facilitate coordination and to be without procompetitive merit; nothing remains for the jury to infer (or to refuse to infer) after the court has defined conspiracy as a matter of law to embrace certain unjustified facilitating conduct, whether unilateral or not. Although such a legal doctrine is defensible and appropriate, [94] the court purported to speak of traditional factual inferences.

More traditional, and also reflecting policy judgments about the social utility of conduct, are those cases that allow a jury to find a conspiracy on the basis of evidence that competitors discussed selling prices, exchanged price lists, and discussed ways to prevent buyers from learning that the volume available was high. This is not mere evidence of conscious parallelism; it is circumstantial evidence of an actual agreement. [95]

In *JTC Petroleum* the Seventh Circuit found sufficient evidence of a relevant conspiracy to upset the district court's grant of summary judgment against the plaintiff. [96] The theory of the complaint (improved by the reasoning of the court) was that applicators of asphalt road materials were fixing the prices of road construction and repair; further, they were compensating the manufacturers of the asphalt to go along with their cartel by refusing to sell to competing applicators, one of whom was the plaintiff. [97] This theory explained why the plaintiff, a competitor of a cartel, could be injured by the cartel. In this case the evidence indicated that the asphalt manufacturers received significantly higher prices for asphalt they sold to the defendant. Further, the asphalt manufacturers refused to sell the plaintiff asphalt for no obvious reason, even when the plaintiff offered to pay cash. These facts were sufficient to create a fact inference that the asphalt producers were being compensated for aiding in the orchestration of a cartel.

Finally, summary judgment in favor of the party with the burden of persuasion is sometimes appropriate, as the Supreme Court held for a per se offense in *Palmer*. [98] Once it appears that a reasonable jury must find each essential element of a violation and that there is no “genuine issue” as to any legally material defense, there is no need for a trial.

308g. Motivation and rationality, especially in conspiracy doctrine..— When competitors expressly contract in writing to, say, boycott the plaintiff, they have by definition conspired. Their conspiracy exists even when it fails to serve their own interests or when rational persons in their situation lack any motive to enter it. [99] Thus, we should not read literally the demand by some courts that the "plaintiff must satisfy the court that the conspiracy which he alleges is, objectively, an economically reasonable one." [100] A "reasonable" conspiracy (in the quoted sense) is one that rational firms in the defendants' situation would (apart from legal constraints) have a motive to form. Such courts do not mean to save defendants who have clearly, though foolishly, conspired. Thus, motivation to conspire is not strictly a necessary condition for a conspiracy finding. As *Matsushita* declared, an unlikely motive negates a conspiracy claim only when the plaintiff fails to "come forward with more persuasive evidence." [101]

As a practical matter, however, a conspiracy's "objective rationality" or motive is a necessary condition for inferring conspiracy from the usual array of evidence, which is generally circumstantial. The courts have wisely recognized that many alleged conspiracies are implausible in that the defendants would not want to enter them even if they were undoubtedly legal. [102] In such cases, it would take very strong evidence indeed to allow a finding that the alleged conspiracy was more likely than not. The 20-year predatory pricing scheme alleged in *Matsushita* seemed so unlikely to pay off for the defendants that the Court doubted their motive to enter that conspiracy. In that case, summary judgment was proper in the absence of more explicit evidence that such a conspiracy had actually occurred.

While conspiratorial motivation is a prerequisite for inferring conspiracy from most circumstantial evidence, such a motive will not support a conspiracy finding. For example, because competitors can profit from conspiring to fix prices, they are deemed to have the motive to do so. If that were sufficient to show conspiracy, then parallel pricing, especially in oligopoly, would be automatically conspiratorial, but it is not. [103] As the *Matsushita* Court explained,

> We do not imply that, if petitioners had had a plausible reason to conspire, ambiguous conduct could suffice to create a triable issue of conspiracy…. [C]onduct that is as consistent with permissible competition as with illegal conspiracy does not, without more, support even an inference of conspiracy. [104]

Thus, proof that competing physicians had a "nonlegitimate" motive for conspiring to exclude the plaintiff physician from a hospital and would "benefit" from doing so would not defeat summary judgment for them unless the evidence also tends to exclude the possibility that the defendants acted independently. [105]

Motive to conspire tends to be negated when a defendant shows that the alleged agreement would harm the alleged conspirators [106] or when the defendant shows "a plausible and justifiable reason for its conduct that is consistent with proper business practice." [107] Thus, natural gas suppliers accepting market prices that were below those in their contracts with a buying pipeline acted consistently with their long-term self-interest in disposing of their gas profitably. [108] Of course, the plaintiff readily gets to the jury when it shows undesirable conduct and market effects unlikely to occur in the absence of conspiracy.

308h. Summary judgment in rule of reason cases..— Most antitrust controversies are subject to the so-called rule of reason, which opens many more issues to inquiry than in per se cases — especially, the final judgment of reasonableness or not. [109] Reasonableness is a mixed question of fact and law that courts nevertheless often leave to the jury. But many rule of reason cases can be decided summarily once the court defines the necessary elements of an unreasonable restraint. Consider a joint research venture by two "small" firms in competition with numerous larger firms in an industry where research is both important and expensive. [110] Because of the obvious efficiency potential, such productive joint venture agreements are presumably lawful. Summary judgment for the defendant is appropriate unless a challenger can show that the venture has significant market

power. [111] Or suppose that a rival firm would like to join the venture although it is as able as the venturers to conduct such research — either because it has the resources individually that the venturers have collectively or because it can form equally efficient ventures with other firms. Expanding the membership increases the danger that the venture will possess market power, while refusing to expand forces the equally able applicant to compete with the venture. Because the venturers' collective refusal to admit this applicant is procompetitive, the court should summarily reject this applicant's complaint that the refusal is an unreasonable restraint or "boycott." [112]

The main point of these examples is that the court considering summary judgment must first decide on the legal doctrine governing the case — for example, that joint research ventures without market power are reasonable and, even if powerful, may refuse to admit rivals who can effectively compete with the venture rather than expand it. That decision will dispose of the case unless the plaintiff offers reasonable proofs escaping the doctrine. When the governing rule conditions legality or a defense on certain elements that may not reasonably be inferred from the pre-trial record, nothing remains to be tried. Summary judgment is then appropriate.

308i. Direct versus circumstantial evidence..— As noted previously, several courts have indicated that "*Matsushita* standards do not apply when the plaintiff has offered direct evidence of conspiracy." [113] To be sure, a conspiracy is undoubtedly established by the signed contract in *Palmer*, [114] assuming, of course, that the written agreement contained all the elements necessary to produce the antitrust violation. [115] But "direct evidence" includes evidence less compelling than a written contract. Consider, for example, a witness testifying that he observed a Chicago meeting between two competitors who promised each other that they would each fix prices at $X. Though direct rather than circumstantial, such evidence does not make conspiracy more likely than not when a dozen disinterested persons saw the witness in a different city at the time of the alleged meeting. Though factual doubts arise most often when the evidence is circumstantial, the *Matsushita* principle holds that there is no genuine issue unless the whole record, including direct and circumstantial evidence, makes a necessary fact more likely than not in the mind of a reasonable juror. As the Third Circuit explained, *Matsushita* distinguishes not between "direct" and "circumstantial" evidence, but between ambiguous and relatively unambiguous evidence. [116]

Footnotes

1 Unless otherwise stated or implied, most of the present Paragraph applies equally to directed verdicts and judgment notwithstanding the verdict (JNOV), which is now known in federal practice as "judgment as a matter of law" (JML). The main difference is that the JNOV or JML typically occurs after rather than prior to trial.

On summary judgment generally, see 10 & 10A Charles A. Wright, Arthur R. Miller & Mary K. Kane, Federal Practice and Procedure (Civil 3d) §§2711 et seq. (1998); William W. Schwarzer, Summary Judgment and Case Management, 56 Antitrust L.J. 213 (1987); William W. Schwarzer, Summary Judgment Under the Federal Rules: Defining Genuine Issues of Material Fact, 99 F.R.D. 465 (1984); Stephen Calkins, Summary Judgment, Motions to Dismiss, and Other Examples of Equilibrating Tendencies in the Antitrust System, 70 Geo. L.J. 1065 (1986).

2 *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

3 Federal Rules of Civil Procedure, Advisory Committee Note on 1963 Amendment to Rule 56(e).

4 *First Natl. Bank of Arizona v. Cities Serv. Co.,* 391 U.S. 253, 289-290 (1968).

5 Readers should consult Wright, Miller & Kane, note 1.

S1 Citing *High-Fructose Corn Syrup,* 295 F.3d 651, 656-657 (7th Cir. 2012) (describing characteristics that make a market susceptible to collusion).

6 *Eastman Kodak Co. v. Image Technical Services, Inc.*, 504 U.S. 451 (1992). See ¶1740.

7 Fed. R. Civ. P.56e-f. See *Perkasie Indus. Corp. v. Advance Transformer, Inc.*, 1992 WL 166042 (E.D. Pa. 1992) (deponent may be cross-examined; if deponent's deposition is modified later, further cross-examination may be permitted); *Sorisio v. Lenox, Inc.*, 701 F. Supp. 950, 955 (D. Conn.), aff'd, 863 F.2d 195 (2d Cir. 1988) (permitting cross-examination of deponent); *Dyer v. MacDougall,* 201 F.2d 265, 266-268 (2d Cir. 1952); *Radio City Music Hall Corp. v. United States,* 135 F.2d 715, 718 (2d Cir. 1943). See 8A C.A. Wright, A.R. Miller, & R.L. Marcus, Federal Practice and Procedure §§2142 et seq. (Civ. 2d 1994).

8 *Petroleum Prods. Antitrust Litig.,* 906 F.2d 432, 438 (9th Cir. 1990), cert. denied, 500 U.S. 959 (1991). Contrast *Midwest Radio Co., Inc. v. Forum Publishing. Co.,* 942 F.2d 1294 (8th Cir. 1991) (a court should not be hesitant to grant summary judgment; and there are no heightened standards to be applied).

9 *United States v. Diebold, Inc.,* 369 U.S. 654 (1962).

10 *Poller v. CBS, Inc.,* 368 U.S. 464, 473 (1962).

11 Ibid. To simplify the presentation, we equate plaintiff with its assignor and ignore the regulatory contingencies in certain contracts.

12 CBS had planned to expand the *B* facilities on its own; it was the plaintiff that had initiated the "trade." As for monopolization, plaintiff's insistence that a UHF station could not survive without network affiliation meant that either *A* or *B* was destined to expire in any event. Monopolizing UHF broadcasting in Milwaukee was implausible because UHF competed with VHF stations, which viewers preferred. Moreover, CBS had no VHF investment in Milwaukee that could be impaired by successful UHF stations; nor could such success overcome consumer preference for VHF stations elsewhere. Nor was it plausible to think that CBS would or could enter UHF in order to strangle it. As for any conspiracy, Bartell was merely a seller, and Holt was merely an agent. See ¶1474.

13 *Poller*, 368 U.S. at 473.

14 E.g., *High Technology Careers v. San Jose Mercury News*, 996 F.2d 987 (9th Cir. 1993) (denying summary judgment to explore defendant newspaper's intent in ceasing to distribute plaintiff's advertising insert while requiring advertisers to deal directly with newspaper).

15 *Norfolk Monument Co. v. Woodlawn Memorial Gardens, Inc.,* 394 U.S. 700 (1969), rev'g 404 F.2d 1008, 1011 (4th Cir. 1968), which states the facts.

16 One court of appeals judge saw a jury question because of consciously parallel, exorbitant fees. 404 F.2d at 1017-1018.

17 See ¶¶1411, 1425. The *Norfolk Monument* dissenter cited Third Circuit language implying that parallelism required submission of the issue to the jury. *Milgram v. Loew's, Inc.,* 192 F.2d 579, 583-584 (3d Cir. 1951), cert. denied, 343 U.S. 929 (1952). He did not cite a later decision from the same court implying the opposite. See *Delaware Valley Marine Supply Co. v. American Tobacco Co.,* 297 F.2d 199, 204-205 (3d Cir. 1961), cert. denied, 369 U.S. 839 (1962). See also Gregory J. Werden, Economic Evidence on the Existence of Collusion: Reconciling Antitrust Law with Oligopoly Theory, 71 Antitrust L.J. 719, 778-780 (2004); Roger D. Blair & Jill Boylston Herndon, Inferring Collusion from Economic Evidence, 2001 Antitrust 17 (Summer 2001); Donald F. Turner, The Definition of Agreement Under the Sherman Act: Conscious Parallelism and Refusals to Deal, 75 Harv. L. Rev. 655 (1962).

18 See ¶¶1426 and 1433.

19 394 U.S. at 704.

20 *First National*, note 4, 391 U.S. at 277.

21 Justice Black dissented, but he was well known for the view that the jury should not be constrained very much by judges. Consider his opinion in *Wilkerson v. McCarthy,* 336 U.S. 53 (1949). See also *Beacon Theatres, Inc. v. Westover,* 359 U.S. 500 (1959); *Dairy Queen v. Wood, Inc.,* 369 U.S. 469 (1962).

22 *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.,* 475 U.S. 574 (1986). See the Symposium on *Matsushita* at Twenty, 38 Loyola L.J. 399 (2007).

23 See, e.g., *Bathke v. Casey's General Stores, Inc.*, 64 F.3d 340, 342 (8th Cir. 1995) ("in complex antitrust cases, no different or heightened standard for the grant of summary judgment applies") (to the extent it is relevant, H.H. was consulted by the defendant).

24 See ¶¶338, 348b.

25 475 U.S. at 586-587.

26 Id. at 591.

27 Ibid.

28 Id. at 585-586. The Court recalled *First National Bank*, note 4: "Since the defendant lacked any rational motive to join the alleged boycott, and since its refusal to deal was consistent with the defendant's independent interest, the refusal to deal could not by itself support a finding of antitrust liability." Id. at 587. For the relevance of motive to conspire, see ¶¶1412, 1434c.

29 Referring to *Monsanto Co. v. Spray-Rite Service Corp*., 465 U.S. 752 (1984), which is discussed in detail at ¶1446.

30 475 U.S. at 588.

31 Requiring plaintiffs to exclude the possibility of defendant's innocence would increase the burden of proof beyond the usual civil standard of "a preponderance of the evidence" to "beyond a reasonable doubt" or even to "certainty." *Monsanto* meant no such revolution, for evidence that "tends to exclude" independent unilateral conduct may allow a jury to tilt the balance of inferences in favor of the alleged conspiracy.

32 *Matsushita*, note 22, at 581.

33 Id.

34 *Tunis Bros. Co. v. Ford Motor Co.,* 763 F.2d 1482, 1495 (3d Cir. 1985), vacated for further consideration in the light of *Matsushita,* 475 U.S. 574 (1986), on remand, 823 F.2d 49 (3d Cir.), cert. denied, 484 U.S. 1060 (1988).

35 *Petroleum Prods*., note 8, at 438. (To the extent it is relevant, P.A.'s views about the meaning and correctness of the Ninth Circuit's decision were sought by the defendants.)

36 *Petroleum Prods*., note 8, at 438.

37 *Brooke Group Ltd v. Brown & Williamson Tobacco Corp*., 509 U.S. 209 (1993) (to the extent it is relevant, P.A. represented the plaintiff on appeal). For fuller discussion of the facts, see ¶¶726, 745.

38 See 509 U.S. at 226.

39 Ibid. Factual disputes on such matters seldom turn on witness credibility or the subjective elements emphasized in *Poller*.

40 *Brooke*, 509 U.S. at 243.

41 *Morristown Block & Concrete Prods. Co. v. General Shale Prods. Corp.,* 829 F.2d 39 (6th Cir. 1987). The quoted language describes much intent evidence. For example, an expressed desire to take business away from rivals does not even tend to prove predatory intent, for taking business away from rivals is inherent in competition. See ¶776.

42 See *Gibson v. Greater Park City Co.,* 818 F.2d 722, 724 (10th Cir. 1987).

43 This is the essence of the *Gibson* court's largely redundant two-part test: (1) if the conspiracy evidence is merely "ambiguous," then the defendant is prima facie entitled to summary judgment unless (2) the plaintiff offers additional evidence that would justify a conspiracy finding by tending to exclude unilateral conduct. Id. at 724. The court applied this test again in *Dreiling v. Peugeot Motors of Am., Inc.,* 850 F.2d 1373 (10th Cir. 1988).

44 *Wilcox v. First Interstate Bank of Or., N.A.,* 815 F.2d 522 (9th Cir. 1987); *T.W. Elec. Serv., Inc. v. PECA,* 809 F.2d 626, 632 (9th Cir. 1987). See also *H.L. Hayden Co. of New York, Inc. v. Siemens Med. Sys., Inc.,* 672 F. Supp. 724, 733 n.12 (S.D.N.Y. 1987), aff'd, 879 F.2d 1005 (2d Cir. 1989) (because alleged scheme between two dealers to convince a supplier to terminate a third dealer seemed more plausible than the *Matsushita* allegation, "plaintiffs need not come forward with more persuasive evidence than would otherwise be necessary to survive defendants' summary judgment motion").

45 *High Fructose Corn Syrup Antitrust Litigation (HFCS)*, 295 F.3d 651 (7th Cir. 2002), cert. denied, 537 U.S. 1188 (2003) (to the extent it is relevant, H.H. was consulted by one defendant after the Seventh Circuit's decision issued). On remand, see *High Fructose Corn Syrup Antitrust Litigation,* 261 F. Supp. 2d 1017 (C.D. Ill. 2003) (denying summary judgment). See also *Ezzo's Invs., Inc. v. Royal Beauty Supply, Inc.*, 94 F.3d 1032 (6th Cir. 1996) (discussed in ¶f ; denying summary judgment after finding vertical conspiracy claim more plausible than the one alleged in *Matsushita*); *Lantec, Inc. v. Novell, Inc.*, 306 F.3d 1003 (10th Cir. 2002) (pre-merger coordination between Novell and Wordperfect did not amount to §2 conspiracy to monopolize when it was equally consistent with independent decision making; JML); *Suzuki of Western Mass., Inc. v. Outdoor Sports Expo.,* 126 F. Supp. 2d 40 (D. Mass. 2001) (MSJ granted because record conclusively showed that boat show promoter's decision favoring certain dealers to display certain boats was unilateral, not product of conspiracy between promoter and favored dealers). See also *TRI, Inc. v. Boise Cascade Office Prods., Inc.*, 315 F.3d 915 (8th Cir.), cert. denied, 539 U.S. 960 (2003) (granting summary judgment for insufficient evidence that distributor conspired with customer not to purchase plaintiff supplier's products; distributor would have no economic motive to conspire); *PepsiCo, Inc. v. Coca*-Cola Co., 315 F.3d 101, 104 (2d Cir. 2002) ("In the context of antitrust cases…summary judgment is particularly favored because of the concern that protracted litigation will chill pro-competitive market forces.").

46 *HFCS*, 295 F.3d at 661, citing *United States v. Andreas*, 216 F.3d 645, 650-654 (7th Cir. 2000), cert. denied, 531 U.S. 1014 (2000); and *Citric Acid Litig.*, 996 F. Supp. 951, 953-954 (N.D. Cal. 1998), aff'd, 191 F.3d 1090 (9th Cir. 1999), cert. denied, 529 U.S. 1037 (2000).

47 *HFCS*, 295 F.3d at 661-662. See also *Vitamins Antitrust Litig.*, 320 F. Supp. 2d 1 (D.D.C. 2004) (denying summary judgment motion on conspiracy claim when conspiracy seemed plausible).

48 Indeed, whenever one essential element can be discovered more simply than the others, the court may properly limit initial discovery to that issue. See ¶311a.

49 *Brooke*, note 37; see ¶726. Many other issues may be involved. Intent may bear on whether below-cost prices are legitimately promotional. Market structure and entry barriers affect recoupment, and the damaged plaintiff must establish and measure its loss. See also *Bathke*, note 23 (summary judgment in predatory pricing claim appropriate once it was clear that evidence of relevant geographic market had failed).

50 *Palmer v. BRG of Ga., Inc.,* 498 U.S. 46 (1990).

51 874 F.2d 1417, 1437 n. 28 (11th Cir. 1989), amended, 893 F.2d 293 (11th Cir. 1990), rev'd, 498 U.S. 46 (1990).

52 Although it was by no means clear, the court might have meant something like this: although the two providers had competed in providing bar review courses, the national firm had not made a profit and decided to withdraw. The interesting question was then whether that withdrawal from competition was a quid pro quo for the remaining firm's decision to use and distribute the withdrawing firm's bar review publications. That question, the court may have believed, was not illuminated very far by the Georgia firm's agreement to remain in Georgia. By contrast, the agreement to stay in Georgia (even by one not intending to expand outside the state) could indicate that the parties had entered into a comprehensive understanding about all aspects of their competition inter se.

The *Petroleum Products* court also noted that "the *Matsushita* standards do not apply when the plaintiff has offered direct evidence of conspiracy." *Petroleum Products*, note 8, 906 F.2d at 441. This observation is

certainly correct to the extent that the direct evidence is sufficient to support a conclusion that conspiracy is more probable than not.

53 *Palmer*, 498 U.S. at 50. Justice Marshall dissented, believing "that summary dispositions deprive litigants of a fair opportunity to be heard on the merits and significantly increase the risk of an erroneous decision." Ibid. He did not indicate what issues needed a trial to resolve, although he might have meant that the facts were less straightforward than the Court indicated. Whether Justice Marshall meant to suggest that summary judgment is *never* appropriate in antitrust cases is not clear.

54 Note 6. This decision is discussed and analyzed in detail in ¶¶1733f and 1740.

55 See Ch. 17C.

56 504 U.S. at 468.

57 Ibid.

58 *Petroleum Products*, note 8, 906 F.2d at 438-440. See also the discussion of the *Citric Acid* case, note 105.

59 *Matsushita*, note 22, 475 U.S. at 584-585, 588-589.

60 *Kodak*, note 6, 504 U.S. at 479.

61 *Monsanto*, note 29, at 763-764. See ¶1454.

62 See note 37.

63 *Big Apple BMW, Inc. v. BMW of North Am., Inc.*, 974 F.2d 1358 (3d Cir. 1992), cert. denied, 507 U.S. 912 (1993). For simplicity, we speak of the manufacturer although the actual defendant was the manufacturer's North American distribution subsidiary.

64 According to the allegations, defendant BMW met with the applicant several times and acceded orally to its request for a dealership but then refused to negotiate further; ended an existing dealership when its lease expired rather than extending the lease and allowing the plaintiff to take over; and delayed its rejection of plaintiff an unreasonably long time. 974 F.2d at 1365-1367.

65 The court pointed to "19 bits" — more than a "mere scintilla" — of conspiracy evidence: existing dealers discussed the plaintiff's various applications, opposed adding another dealership, and expressed these views to BMW on more than one occasion. Id. at 1363, 1367, 1385-1386.

66 See ¶1611.

67 974 F.2d at 1375-1376.

68 *Lovett v. General Motors Corp.*, 998 F.2d 575 (8th Cir. 1993), cert. denied, 510 U.S. 1113 (1994). See also *Alvord-Polk, Inc. v. F. Schumacher & Co.*, 37 F.3d 996 (3d Cir. 1994), cert. denied, 514 U.S. 1063 (1995) (finding sufficient fact issues to support inference of conspiracy in trade association protests against "800-number" dealers who sell wallpaper at discounts by free-riding on stocking and displays of defendant dealers); *Rosefielde v. Falcon Jet Corp.,* 701 F. Supp. 1053 (D.N.J. 1988) (finding fact issues supporting inference of price-fixing conspiracy).

69 See Ch. 16E.

70 See ¶1653.

71 E.g., *Snyder v. Howard Johnson's Motor Lodges, Inc.,* 412 F. Supp. 724 (S.D. Ill. 1976) (denying summary judgment in favor of franchisor who opened a business competing with plaintiff franchisee, who is to have opportunity of proving defendant's anticompetitive intent).

72 *Ezzo's Invs., Inc. v. Royal Beauty Supply, Inc.*, 94 F.3d 1032 (6th Cir. 1996).

73 *Matsushita*, note 22, 475 U.S. at 588.

74 *Ezzo's*, 94 F.3d at 1036.

75 Id.

76 See ¶¶1411 and 1433.

77 *Richards v. Neilsen Freight Lines,* 810 F.2d 898, 902 (9th Cir. 1987). See ¶¶1413-1415. Some courts go even further.

78 *City of Long Beach v. Standard Oil Co. of Cal.,* 872 F.2d 1401, 1406, 1407 (9th Cir.), amended, 886 F.2d 246 (9th Cir. 1989), cert. denied, 493 U.S. 1076 (1990), reversed summary judgment for refiners charged with agreeing on the prices they paid the plaintiff for crude oil. The court did not object to exchanges by which a refiner with oil at one place would provide some to a rival without oil there, while the latter would provide oil to the former at a different location. Although they had to settle in cash when the quality or quantity of the exchanges did not fully match, the court believed that the settlement formulas were more cumbersome than normal or necessary and had the effect of depressing the prices paid the plaintiff.

79 *Petruzzi's IGA Supermarkets, Inc. v. Darling-Delaware Co., Inc.*, 998 F.2d 1224, 1232 (3d Cir.), cert. denied, 510 U.S. 994 (1993).

80 Quoting *Petroleum Products*, note 8, 906 F.2d at 439.

81 *Petruzzi's*, 998 F.2d at 1232.

82 Ibid. On buyers' cartels, see ¶¶2010-2015.

83 Citing *Matsushita*, note 22, 475 U.S. at 597.

84 *Petruzzi's*, 998 F.2d at 1233.

85 Id. at 1242. See also *Instructional Sys. Dev. Corp. v. Aetna Cas. & Sur. Co.*, 817 F.2d 639, 646 (10th Cir. 1987) (*Matsushita* holding was based on twin premises of an alleged conspiracy that was fundamentally irrational and ambiguous circumstantial evidence; as the rationality of the alleged conspiracy increases, the evidentiary burden is lessened). In *H.J.*, the Eighth Circuit went even further, suggesting that *Matsushita* "does not apply" in a case where the alleged conspiracy seems quite rational. *H.J., Inc. v. International Tel. & Tel. Corp.*, 867 F.2d 1531, 1544 n.10 (8th Cir. 1989) ("There is no claim in this case that the supposed conspiracy makes no economic sense. *Matsushita Electric* does not apply.").

86 *Matsushita*, note 22, 475 U.S. at 597.

87 Id. at 596-597.

88 For example, evidence that gasoline stations with publicly posted prices changed their prices in lockstep is equally consistent with the propositions that (1) they are fixing prices, or (2) they are merely following the prices of a tacitly acknowledged leader. Standing alone, such evidence would not create a fact issue of conspiracy even in a concentrated market, where a cartel agreement would be quite rational.

89 See ¶725a.

90 See ¶¶1429-1431.

91 See ¶¶1432-1434.

92 See ¶1435. But see *Blomkest Fertilizer, Inc. v. Potash Corp. of Saskatchewan*, 203 F.3d 1028 (8th Cir. 2000) (en banc), cert. denied, 531 U.S. 815 (2000), which found insufficient evidence of a price-fixing conspiracy to survive the defendant's summary judgment motion. The majority was most disturbed by inter-competitor price-verification calls made in a tight oligopoly of producers of a fungible product; however, it concluded that there was insufficient evidence that any particular price increase resulted from a specific price-verification call. The dissenters found this requirement too strenuous and appeared ready to condemn significant use of direct price verification in an oligopoly market for a commodity.

93 *Petroleum Products*, note 8.

94 See ¶1436.

95 *Bulk Popcorn Antitrust Litig.*, 783 F. Supp. 1194 (D. Minn. 1991) (facts that popcorn supplier's employees discussed prices with competitors, exchanged price lists and at least discussed joint attempts to prevent

public dissemination of information showing wide availability of popcorn was sufficient to undermine defendant's summary judgment motion against price-fixing claim). But see *Blomkest*, note 92.

96 *JTC Petroleum Co. v. Piasa Motor Fuels, Inc.*, 190 F.3d 775 (7th Cir. 1999).

97 Id. at 778.

98 Note 50.

99 See the discussion of the Supreme Court's *Palmer* decision, note 50.

100 See *Helicopter Support Sys., Inc. v. Hughes Helicopter, Inc.,* 818 F.2d 1530, 1534 (11th Cir. 1987).

101 *Matsushita*, note 22, 475 U.S. at 587. At the pleading stage, of course, the complaint need not offer a plausible reason for the defendants' conspiracy but "merely needs to allege that they did indeed conspire and give some factual allegations that would support such a claim." *Dillard v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 961 F.2d 1148, 1159 (5th Cir. 1992), cert. denied, 506 U.S. 1079 (1993) (no dismissal of complaint alleging parallel and interdependent use of substantially identical contract clauses after collective dissemination of information about such clauses). On summary disposition before discovery, see ¶307.

102 See ¶1412.

103 See ¶¶1412 and 1434c.

104 *Matsushita*, note 22, at 597 n.21.

105 *Bolt v. Halifax Hosp. Medical Center,* 891 F.2d 810, 819 (11th Cir.), cert. denied, 495 U.S. 924 (1990). The court added that this §1 plaintiff "need not prove an intent on the part of the co-conspirators to restrain trade or build a monopoly"; if the "purported conspiracy has an anticompetitive effect, the plaintiff has made out a case…." Id. at 820.

See also *Citric Acid Litig.*, 191 F.3d 1090 (9th Cir. 1999), cert. denied, 529 U.S. 1037 (2000), concluding that one could not infer that Cargill participated in an antitrust conspiracy from the fact that it slowed down its capacity expansion; court noted some questions about timing but also that Cargill did in fact expand its capacity rapidly during the conspiracy period, although not so rapidly as it originally intended to do. The plaintiffs believed that allegations concerning Cargill's conduct were not inherently implausible, nor was the slowing of its capacity expansion a procompetitive act. But the Ninth Circuit found this insufficient, noting that there were both collusive and noncollusive plausible explanations for Cargill's actions. Indeed, such evidence rarely proves anything unless accompanied by more explicit evidence of cartel participation. Suppose four out of five firms in a market fix prices, while the fifth does not participate. In response to the cartel's output reduction and price increase, the nonparticipant will settle on its own profit-maximizing strategy, which may involve rapid expansion of capacity-restoring output toward the competitive level. But it would even more likely be a strategy of permitting its own price to rise to something approaching that of the cartel, and this may involve producing greater, the same amount, or less than it did before the conspiracy period.

The court also held that the mere fact that the non-settling defendant was a member of a trade association and that association may have been a front for a cartel was insufficient to establish defendant's participation; in fact, most of the meetings of the acknowledged cartel took place away from the trade association, and in which non-settling defendant did not participate; and there were many benefits to joining the association other than participation in a conspiracy. See also the brief per curiam statement on the denial of rehearing, stating that the petitioners' suggestion that the court should have applied the summary judgment standard as modified by *Kodak*:

> We believe this argument is misplaced. Although the *Kodak* Court explained the holding of *Matsushita*, it did not redefine *Matsushita*'s summary judgment standard. Moreover, as the Court noted, the "principal issue" in *Kodak* related to tying and market power. Id. at 455. *Kodak* was not concerned with the sufficiency of evidence of conspiratorial acts alleged under §1 of the Sherman Act.

106 E.g., *Eichman v. Fotomat Corp*., 880 F.2d 149, 161 (9th Cir. 1989) (implausible that film processors conspired with franchisor Fotomat to destroy franchisees who became processors' increasingly important customers as Fotomat shifted to self-processing). Although the Eleventh Circuit approved a directed verdict against a plaintiff with insufficient evidence of a resale price maintenance agreement, the court erred in thinking that such an agreement could bring the manufacturer and dealer "monopoly profits." See *Winn v. Edna Hibel Corp.,* 858 F.2d 1517, 1520 (11th Cir. 1988). Insulating a dealer from intrabrand price competition might sometimes increase efficiency but excess profit for dealers harms the manufacturer. See ¶1603.

107 *Richards*, note 77, 810 F.2d at 902 (once a defendant makes that showing, "a plaintiff must provide specific factual support for its allegations of conspiracy tending to show that the defendant was not acting independently"). See *Merck-Medco Managed Care, LLC v. Rite Aid Corp*., 201 F.3d 436, 1999-2 Trade Cas. ¶72,640, 1999 WL 691840 (4th Cir. 1999, unpublished) (allegations that pharmacies conspired not to participate in plaintiff's prepaid pharmaceuticals plan; (1) conspiracy was plausible, in that pharmacies could maintain higher prices by collectively refusing to participate — although if only one or a few refused, they would simply lose the business; (2) there was conscious parallelism because each pharmacy knew that if others failed to participate the plan as a whole would fail; (3) plenty of interfirm contacts; (4) however, this evidence was amply rebutted by statements by individual defendants to the effect that participation would be very costly to them and that the interfirm contacts were concerned other matters; summary judgment granted).

108 *Cayman Exploration Corp. v. United Gas Pipe Line Co.,* 873 F.2d 1357 (10th Cir. 1989). Cf. *Corner Pocket of Sioux Falls, Inc. v. Video Lottery Technologies, Inc.*, 123 F.3d 1107 (8th Cir. 1997), cert. denied, 522 U.S. 1117 (1998) (in order to avoid summary judgment under *Matsushita* a plaintiff must show not merely that the alleged conspiracy makes economic sense, but if the only evidence is circumstantial, that the acts are not consistent with individual self-interest; citing an earlier version of this Paragraph).

109 See Ch. 15.

110 On research joint ventures, see ¶2115.

111 See ¶1503. Once the plaintiff shows such power and the defendant documents the efficiencies, the plaintiff must persuade the tribunal that the venture is reasonably likely to lead to higher prices or lesser quality. See ¶1507.

112 See ¶¶2214.

113 E.g., *Petroleum Products*, note 8, 906 F.2d at 441.

114 See note 50.

115 The caveat is necessary because some written agreements fail to show elements essential to the antitrust claim, such as coercion in a tying case. For example, in a case challenging tying, a written contract under which the plaintiff agrees to purchase " *A* + *B*" does not itself show that the plaintiff was forced to do so. See, e.g., *Paramount Pictures Corp. v. Johnson Broadcasting Inc*., 2006-1 Trade Cas. ¶75,236 (S.D. Tex. Feb. 15, 2006) (denying summary judgment on block-booking claim where it could not be inferred from the written contract whether the plaintiff had licensed three shows because it was forced to or whether it did so willingly).

116 *Petruzzi's*, note 79, 998 F.2d at 1233.

EXHIBIT 240

Horizontal Merger Guidelines

U.S. Department of Justice

and the

Federal Trade Commission

Issued: August 19, 2010

Table of Contents

1. Overview

These Guidelines outline the principal analytical techniques, practices, and the enforcement policy of the Department of Justice and the Federal Trade Commission (the "Agencies") with respect to mergers and acquisitions involving actual or potential competitors ("horizontal mergers") under the federal antitrust laws.[1] The relevant statutory provisions include Section 7 of the Clayton Act, 15 U.S.C. § 18, Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2, and Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45. Most particularly, Section 7 of the Clayton Act prohibits mergers if "in any line of commerce or in any activity affecting commerce in any section of the country, the effect of such acquisition may be substantially to lessen competition, or to tend to create a monopoly."

The Agencies seek to identify and challenge competitively harmful mergers while avoiding unnecessary interference with mergers that are either competitively beneficial or neutral. Most merger analysis is necessarily predictive, requiring an assessment of what will likely happen if a merger proceeds as compared to what will likely happen if it does not. Given this inherent need for prediction, these Guidelines reflect the congressional intent that merger enforcement should interdict competitive problems in their incipiency and that certainty about anticompetitive effect is seldom possible and not required for a merger to be illegal.

These Guidelines describe the principal analytical techniques and the main types of evidence on which the Agencies usually rely to predict whether a horizontal merger may substantially lessen competition. They are not intended to describe how the Agencies analyze cases other than horizontal mergers. These Guidelines are intended to assist the business community and antitrust practitioners by increasing the transparency of the analytical process underlying the Agencies' enforcement decisions. They may also assist the courts in developing an appropriate framework for interpreting and applying the antitrust laws in the horizontal merger context.

These Guidelines should be read with the awareness that merger analysis does not consist of uniform application of a single methodology. Rather, it is a fact-specific process through which the Agencies, guided by their extensive experience, apply a range of analytical tools to the reasonably available and reliable evidence to evaluate competitive concerns in a limited period of time. Where these Guidelines provide examples, they are illustrative and do not exhaust the applications of the relevant principle.[2]

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[1] These Guidelines replace the Horizontal Merger Guidelines issued in 1992, revised in 1997. They reflect the ongoing accumulation of experience at the Agencies. The Commentary on the Horizontal Merger Guidelines issued by the Agencies in 2006 remains a valuable supplement to these Guidelines. These Guidelines may be revised from time to time as necessary to reflect significant changes in enforcement policy, to clarify existing policy, or to reflect new learning. These Guidelines do not cover vertical or other types of non-horizontal acquisitions.

[2] These Guidelines are not intended to describe how the Agencies will conduct the litigation of cases they decide to bring. Although relevant in that context, these Guidelines neither dictate nor exhaust the range of evidence the Agencies may introduce in litigation.

The unifying theme of these Guidelines is that mergers should not be permitted to create, enhance, or entrench market power or to facilitate its exercise. For simplicity of exposition, these Guidelines generally refer to all of these effects as enhancing market power. A merger enhances market power if it is likely to encourage one or more firms to raise price, reduce output, diminish innovation, or otherwise harm customers as a result of diminished competitive constraints or incentives. In evaluating how a merger will likely change a firm's behavior, the Agencies focus primarily on how the merger affects conduct that would be most profitable for the firm.

A merger can enhance market power simply by eliminating competition between the merging parties. This effect can arise even if the merger causes no changes in the way other firms behave. Adverse competitive effects arising in this manner are referred to as "unilateral effects." A merger also can enhance market power by increasing the risk of coordinated, accommodating, or interdependent behavior among rivals. Adverse competitive effects arising in this manner are referred to as "coordinated effects." In any given case, either or both types of effects may be present, and the distinction between them may be blurred.

These Guidelines principally describe how the Agencies analyze mergers between rival suppliers that may enhance their market power as sellers. Enhancement of market power by sellers often elevates the prices charged to customers. For simplicity of exposition, these Guidelines generally discuss the analysis in terms of such price effects. Enhanced market power can also be manifested in non-price terms and conditions that adversely affect customers, including reduced product quality, reduced product variety, reduced service, or diminished innovation. Such non-price effects may coexist with price effects, or can arise in their absence. When the Agencies investigate whether a merger may lead to a substantial lessening of non-price competition, they employ an approach analogous to that used to evaluate price competition. Enhanced market power may also make it more likely that the merged entity can profitably and effectively engage in exclusionary conduct. Regardless of how enhanced market power likely would be manifested, the Agencies normally evaluate mergers based on their impact on customers. The Agencies examine effects on either or both of the direct customers and the final consumers. The Agencies presume, absent convincing evidence to the contrary, that adverse effects on direct customers also cause adverse effects on final consumers.

Enhancement of market power by buyers, sometimes called "monopsony power," has adverse effects comparable to enhancement of market power by sellers. The Agencies employ an analogous framework to analyze mergers between rival purchasers that may enhance their market power as buyers. See Section 12.

2. Evidence of Adverse Competitive Effects

The Agencies consider any reasonably available and reliable evidence to address the central question of whether a merger may substantially lessen competition. This section discusses several categories and sources of evidence that the Agencies, in their experience, have found most informative in predicting the likely competitive effects of mergers. The list provided here is not exhaustive. In any given case, reliable evidence may be available in only some categories or from some sources. For each category of evidence, the Agencies consider evidence indicating that the merger may enhance competition as well as evidence indicating that it may lessen competition.

2.1 Types of Evidence

2.1.1 Actual Effects Observed in Consummated Mergers

When evaluating a consummated merger, the ultimate issue is not only whether adverse competitive effects have already resulted from the merger, but also whether such effects are likely to arise in the future. Evidence of observed post-merger price increases or other changes adverse to customers is given substantial weight. The Agencies evaluate whether such changes are anticompetitive effects resulting from the merger, in which case they can be dispositive. However, a consummated merger may be anticompetitive even if such effects have not yet been observed, perhaps because the merged firm may be aware of the possibility of post-merger antitrust review and moderating its conduct. Consequently, the Agencies also consider the same types of evidence they consider when evaluating unconsummated mergers.

2.1.2 Direct Comparisons Based on Experience

The Agencies look for historical events, or "natural experiments," that are informative regarding the competitive effects of the merger. For example, the Agencies may examine the impact of recent mergers, entry, expansion, or exit in the relevant market. Effects of analogous events in similar markets may also be informative.

The Agencies also look for reliable evidence based on variations among similar markets. For example, if the merging firms compete in some locales but not others, comparisons of prices charged in regions where they do and do not compete may be informative regarding post-merger prices. In some cases, however, prices are set on such a broad geographic basis that such comparisons are not informative. The Agencies also may examine how prices in similar markets vary with the number of significant competitors in those markets.

2.1.3 Market Shares and Concentration in a Relevant Market

The Agencies give weight to the merging parties' market shares in a relevant market, the level of concentration, and the change in concentration caused by the merger. See Sections 4 and 5. Mergers that cause a significant increase in concentration and result in highly concentrated markets are presumed to be likely to enhance market power, but this presumption can be rebutted by persuasive evidence showing that the merger is unlikely to enhance market power.

2.1.4 Substantial Head-to-Head Competition

The Agencies consider whether the merging firms have been, or likely will become absent the merger, substantial head-to-head competitors. Such evidence can be especially relevant for evaluating adverse unilateral effects, which result directly from the loss of that competition. See Section 6. This evidence can also inform market definition. See Section 4.

2.1.5 Disruptive Role of a Merging Party

The Agencies consider whether a merger may lessen competition by eliminating a "maverick" firm, i.e., a firm that plays a disruptive role in the market to the benefit of customers. For example, if one of the merging firms has a strong incumbency position and the other merging firm threatens to

disrupt market conditions with a new technology or business model, their merger can involve the loss of actual or potential competition. Likewise, one of the merging firms may have the incentive to take the lead in price cutting or other competitive conduct or to resist increases in industry prices. A firm that may discipline prices based on its ability and incentive to expand production rapidly using available capacity also can be a maverick, as can a firm that has often resisted otherwise prevailing industry norms to cooperate on price setting or other terms of competition.

2.2 Sources of Evidence

The Agencies consider many sources of evidence in their merger analysis. The most common sources of reasonably available and reliable evidence are the merging parties, customers, other industry participants, and industry observers.

2.2.1 Merging Parties

The Agencies typically obtain substantial information from the merging parties. This information can take the form of documents, testimony, or data, and can consist of descriptions of competitively relevant conditions or reflect actual business conduct and decisions. Documents created in the normal course are more probative than documents created as advocacy materials in merger review. Documents describing industry conditions can be informative regarding the operation of the market and how a firm identifies and assesses its rivals, particularly when business decisions are made in reliance on the accuracy of those descriptions. The business decisions taken by the merging firms also can be informative about industry conditions. For example, if a firm sets price well above incremental cost, that normally indicates either that the firm believes its customers are not highly sensitive to price (not in itself of antitrust concern, see Section 4.1.3[3]) or that the firm and its rivals are engaged in coordinated interaction (see Section 7). Incremental cost depends on the relevant increment in output as well as on the time period involved, and in the case of large increments and sustained changes in output it may include some costs that would be fixed for smaller increments of output or shorter time periods.

Explicit or implicit evidence that the merging parties intend to raise prices, reduce output or capacity, reduce product quality or variety, withdraw products or delay their introduction, or curtail research and development efforts after the merger, or explicit or implicit evidence that the ability to engage in such conduct motivated the merger, can be highly informative in evaluating the likely effects of a merger. Likewise, the Agencies look for reliable evidence that the merger is likely to result in efficiencies. The Agencies give careful consideration to the views of individuals whose responsibilities, expertise, and experience relating to the issues in question provide particular indicia of reliability. The financial terms of the transaction may also be informative regarding competitive effects. For example, a purchase price in excess of the acquired firm's stand-alone market value may indicate that the acquiring firm is paying a premium because it expects to be able to reduce competition or to achieve efficiencies.

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[3] High margins commonly arise for products that are significantly differentiated. Products involving substantial fixed costs typically will be developed only if suppliers expect there to be enough differentiation to support margins sufficient to cover those fixed costs. High margins can be consistent with incumbent firms earning competitive returns.

2.2.2 Customers

Customers can provide a variety of information to the Agencies, ranging from information about their own purchasing behavior and choices to their views about the effects of the merger itself.

Information from customers about how they would likely respond to a price increase, and the relative attractiveness of different products or suppliers, may be highly relevant, especially when corroborated by other evidence such as historical purchasing patterns and practices. Customers also can provide valuable information about the impact of historical events such as entry by a new supplier.

The conclusions of well-informed and sophisticated customers on the likely impact of the merger itself can also help the Agencies investigate competitive effects, because customers typically feel the consequences of both competitively beneficial and competitively harmful mergers. In evaluating such evidence, the Agencies are mindful that customers may oppose, or favor, a merger for reasons unrelated to the antitrust issues raised by that merger.

When some customers express concerns about the competitive effects of a merger while others view the merger as beneficial or neutral, the Agencies take account of this divergence in using the information provided by customers and consider the likely reasons for such divergence of views. For example, if for regulatory reasons some customers cannot buy imported products, while others can, a merger between domestic suppliers may harm the former customers even if it leaves the more flexible customers unharmed. See Section 3.

When direct customers of the merging firms compete against one another in a downstream market, their interests may not be aligned with the interests of final consumers, especially if the direct customers expect to pass on any anticompetitive price increase. A customer that is protected from adverse competitive effects by a long-term contract, or otherwise relatively immune from the merger's harmful effects, may even welcome an anticompetitive merger that provides that customer with a competitive advantage over its downstream rivals.

> *Example 1:* As a result of the merger, Customer C will experience a price increase for an input used in producing its final product, raising its costs. Customer C's rivals use this input more intensively than Customer C, and the same price increase applied to them will raise their costs more than it raises Customer C's costs. On balance, Customer C may benefit from the merger even though the merger involves a substantial lessening of competition.

2.2.3 Other Industry Participants and Observers

Suppliers, indirect customers, distributors, other industry participants, and industry analysts can also provide information helpful to a merger inquiry. The interests of firms selling products complementary to those offered by the merging firms often are well aligned with those of customers, making their informed views valuable.

Information from firms that are rivals to the merging parties can help illuminate how the market operates. The interests of rival firms often diverge from the interests of customers, since customers normally lose, but rival firms gain, if the merged entity raises its prices. For that reason, the Agencies do not routinely rely on the overall views of rival firms regarding the competitive effects of the

merger. However, rival firms may provide relevant facts, and even their overall views may be instructive, especially in cases where the Agencies are concerned that the merged entity may engage in exclusionary conduct.

> *Example 2:* Merging Firms A and B operate in a market in which network effects are significant, implying that any firm's product is significantly more valuable if it commands a large market share or if it is interconnected with others that in aggregate command such a share. Prior to the merger, they and their rivals voluntarily interconnect with one another. The merger would create an entity with a large enough share that a strategy of ending voluntary interconnection would have a dangerous probability of creating monopoly power in this market. The interests of rivals and of consumers would be broadly aligned in preventing such a merger.

3. Targeted Customers and Price Discrimination

When examining possible adverse competitive effects from a merger, the Agencies consider whether those effects vary significantly for different customers purchasing the same or similar products. Such differential impacts are possible when sellers can discriminate, e.g., by profitably raising price to certain targeted customers but not to others. The possibility of price discrimination influences market definition (see Section 4), the measurement of market shares (see Section 5), and the evaluation of competitive effects (see Sections 6 and 7).

When price discrimination is feasible, adverse competitive effects on targeted customers can arise, even if such effects will not arise for other customers. A price increase for targeted customers may be profitable even if a price increase for all customers would not be profitable because too many other customers would substitute away. When discrimination is reasonably likely, the Agencies may evaluate competitive effects separately by type of customer. The Agencies may have access to information unavailable to customers that is relevant to evaluating whether discrimination is reasonably likely.

For price discrimination to be feasible, two conditions typically must be met: differential pricing and limited arbitrage.

First, the suppliers engaging in price discrimination must be able to price differently to targeted customers than to other customers. This may involve identification of individual customers to which different prices are offered or offering different prices to different types of customers based on observable characteristics.

> *Example 3:* Suppliers can distinguish large buyers from small buyers. Large buyers are more likely than small buyers to self-supply in response to a significant price increase. The merger may lead to price discrimination against small buyers, harming them, even if large buyers are not harmed. Such discrimination can occur even if there is no discrete gap in size between the classes of large and small buyers.

In other cases, suppliers may be unable to distinguish among different types of customers but can offer multiple products that sort customers based on their purchase decisions.

Second, the targeted customers must not be able to defeat the price increase of concern by arbitrage, e.g., by purchasing indirectly from or through other customers. Arbitrage may be difficult if it would void warranties or make service more difficult or costly for customers. Arbitrage is inherently impossible for many services. Arbitrage between customers at different geographic locations may be

impractical due to transportation costs. Arbitrage on a modest scale may be possible but sufficiently costly or limited that it would not deter or defeat a discriminatory pricing strategy.

4. Market Definition

When the Agencies identify a potential competitive concern with a horizontal merger, market definition plays two roles. First, market definition helps specify the line of commerce and section of the country in which the competitive concern arises. In any merger enforcement action, the Agencies will normally identify one or more relevant markets in which the merger may substantially lessen competition. Second, market definition allows the Agencies to identify market participants and measure market shares and market concentration. See Section 5. The measurement of market shares and market concentration is not an end in itself, but is useful to the extent it illuminates the merger's likely competitive effects.

The Agencies' analysis need not start with market definition. Some of the analytical tools used by the Agencies to assess competitive effects do not rely on market definition, although evaluation of competitive alternatives available to customers is always necessary at some point in the analysis.

Evidence of competitive effects can inform market definition, just as market definition can be informative regarding competitive effects. For example, evidence that a reduction in the number of significant rivals offering a group of products causes prices for those products to rise significantly can itself establish that those products form a relevant market. Such evidence also may more directly predict the competitive effects of a merger, reducing the role of inferences from market definition and market shares.

Where analysis suggests alternative and reasonably plausible candidate markets, and where the resulting market shares lead to very different inferences regarding competitive effects, it is particularly valuable to examine more direct forms of evidence concerning those effects.

Market definition focuses solely on demand substitution factors, i.e., on customers' ability and willingness to substitute away from one product to another in response to a price increase or a corresponding non-price change such as a reduction in product quality or service. The responsive actions of suppliers are also important in competitive analysis. They are considered in these Guidelines in the sections addressing the identification of market participants, the measurement of market shares, the analysis of competitive effects, and entry.

Customers often confront a range of possible substitutes for the products of the merging firms. Some substitutes may be closer, and others more distant, either geographically or in terms of product attributes and perceptions. Additionally, customers may assess the proximity of different products differently. When products or suppliers in different geographic areas are substitutes for one another to varying degrees, defining a market to include some substitutes and exclude others is inevitably a simplification that cannot capture the full variation in the extent to which different products compete against each other. The principles of market definition outlined below seek to make this inevitable simplification as useful and informative as is practically possible. Relevant markets need not have precise metes and bounds.

Defining a market broadly to include relatively distant product or geographic substitutes can lead to misleading market shares. This is because the competitive significance of distant substitutes is unlikely to be commensurate with their shares in a broad market. Although excluding more distant substitutes from the market inevitably understates their competitive significance to some degree, doing so often provides a more accurate indicator of the competitive effects of the merger than would the alternative of including them and overstating their competitive significance as proportional to their shares in an expanded market.

> *Example 4:* Firms A and B, sellers of two leading brands of motorcycles, propose to merge. If Brand A motorcycle prices were to rise, some buyers would substitute to Brand B, and some others would substitute to cars. However, motorcycle buyers see Brand B motorcycles as much more similar to Brand A motorcycles than are cars. Far more cars are sold than motorcycles. Evaluating shares in a market that includes cars would greatly underestimate the competitive significance of Brand B motorcycles in constraining Brand A's prices and greatly overestimate the significance of cars.

Market shares of different products in narrowly defined markets are more likely to capture the relative competitive significance of these products, and often more accurately reflect competition between close substitutes. As a result, properly defined antitrust markets often exclude some substitutes to which some customers might turn in the face of a price increase even if such substitutes provide alternatives for those customers. However, a group of products is too narrow to constitute a relevant market if competition from products outside that group is so ample that even the complete elimination of competition within the group would not significantly harm either direct customers or downstream consumers. The hypothetical monopolist test (see Section 4.1.1) is designed to ensure that candidate markets are not overly narrow in this respect.

The Agencies implement these principles of market definition flexibly when evaluating different possible candidate markets. Relevant antitrust markets defined according to the hypothetical monopolist test are not always intuitive and may not align with how industry members use the term "market."

Section 4.1 describes the principles that apply to product market definition, and gives guidance on how the Agencies most often apply those principles. Section 4.2 describes how the same principles apply to geographic market definition. Although discussed separately for simplicity of exposition, the principles described in Sections 4.1 and 4.2 are combined to define a relevant market, which has both a product and a geographic dimension. In particular, the hypothetical monopolist test is applied to a group of products together with a geographic region to determine a relevant market.

4.1 Product Market Definition

When a product sold by one merging firm (Product A) competes against one or more products sold by the other merging firm, the Agencies define a relevant product market around Product A to evaluate the importance of that competition. Such a relevant product market consists of a group of substitute products including Product A. Multiple relevant product markets may thus be identified.

4.1.1 The Hypothetical Monopolist Test

The Agencies employ the hypothetical monopolist test to evaluate whether groups of products in candidate markets are sufficiently broad to constitute relevant antitrust markets. The Agencies use the

hypothetical monopolist test to identify a set of products that are reasonably interchangeable with a product sold by one of the merging firms.

The hypothetical monopolist test requires that a product market contain enough substitute products so that it could be subject to post-merger exercise of market power significantly exceeding that existing absent the merger. Specifically, the test requires that a hypothetical profit-maximizing firm, not subject to price regulation, that was the only present and future seller of those products ("hypothetical monopolist") likely would impose at least a small but significant and non-transitory increase in price ("SSNIP") on at least one product in the market, including at least one product sold by one of the merging firms.[4] For the purpose of analyzing this issue, the terms of sale of products outside the candidate market are held constant. The SSNIP is employed solely as a methodological tool for performing the hypothetical monopolist test; it is not a tolerance level for price increases resulting from a merger.

Groups of products may satisfy the hypothetical monopolist test without including the full range of substitutes from which customers choose. The hypothetical monopolist test may identify a group of products as a relevant market even if customers would substitute significantly to products outside that group in response to a price increase.

> *Example 5:* Products A and B are being tested as a candidate market. Each sells for $100, has an incremental cost of $60, and sells 1200 units. For every dollar increase in the price of Product A, for any given price of Product B, Product A loses twenty units of sales to products outside the candidate market and ten units of sales to Product B, and likewise for Product B. Under these conditions, economic analysis shows that a hypothetical profit-maximizing monopolist controlling Products A and B would raise both of their prices by ten percent, to $110. Therefore, Products A and B satisfy the hypothetical monopolist test using a five percent SSNIP, and indeed for any SSNIP size up to ten percent. This is true even though two-thirds of the sales lost by one product when it raises its price are diverted to products outside the relevant market.

When applying the hypothetical monopolist test to define a market around a product offered by one of the merging firms, if the market includes a second product, the Agencies will normally also include a third product if that third product is a closer substitute for the first product than is the second product. The third product is a closer substitute if, in response to a SSNIP on the first product, greater revenues are diverted to the third product than to the second product.

> *Example 6:* In Example 5, suppose that half of the unit sales lost by Product A when it raises its price are diverted to Product C, which also has a price of $100, while one-third are diverted to Product B. Product C is a closer substitute for Product A than is Product B. Thus Product C will normally be included in the relevant market, even though Products A and B together satisfy the hypothetical monopolist test.

The hypothetical monopolist test ensures that markets are not defined too narrowly, but it does not lead to a single relevant market. The Agencies may evaluate a merger in any relevant market

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[4] If the pricing incentives of the firms supplying the products in the candidate market differ substantially from those of the hypothetical monopolist, for reasons other than the latter's control over a larger group of substitutes, the Agencies may instead employ the concept of a hypothetical profit-maximizing cartel comprised of the firms (with all their products) that sell the products in the candidate market. This approach is most likely to be appropriate if the merging firms sell products outside the candidate market that significantly affect their pricing incentives for products in the candidate market. This could occur, for example, if the candidate market is one for durable equipment and the firms selling that equipment derive substantial net revenues from selling spare parts and service for that equipment.

satisfying the test, guided by the overarching principle that the purpose of defining the market and measuring market shares is to illuminate the evaluation of competitive effects. Because the relative competitive significance of more distant substitutes is apt to be overstated by their share of sales, when the Agencies rely on market shares and concentration, they usually do so in the smallest relevant market satisfying the hypothetical monopolist test.

> *Example 7:* In Example 4, including cars in the market will lead to misleadingly small market shares for motorcycle producers. Unless motorcycles fail the hypothetical monopolist test, the Agencies would not include cars in the market in analyzing this motorcycle merger.

4.1.2 Benchmark Prices and SSNIP Size

The Agencies apply the SSNIP starting from prices that would likely prevail absent the merger. If prices are not likely to change absent the merger, these benchmark prices can reasonably be taken to be the prices prevailing prior to the merger.[5] If prices are likely to change absent the merger, e.g., because of innovation or entry, the Agencies may use anticipated future prices as the benchmark for the test. If prices might fall absent the merger due to the breakdown of pre-merger coordination, the Agencies may use those lower prices as the benchmark for the test. In some cases, the techniques employed by the Agencies to implement the hypothetical monopolist test focus on the difference in incentives between pre-merger firms and the hypothetical monopolist and do not require specifying the benchmark prices.

The SSNIP is intended to represent a "small but significant" increase in the prices charged by firms in the candidate market for the value they contribute to the products or services used by customers. This properly directs attention to the effects of price changes commensurate with those that might result from a significant lessening of competition caused by the merger. This methodology is used because normally it is possible to quantify "small but significant" adverse price effects on customers and analyze their likely reactions, not because price effects are more important than non-price effects.

The Agencies most often use a SSNIP of five percent of the price paid by customers for the products or services to which the merging firms contribute value. However, what constitutes a "small but significant" increase in price, commensurate with a significant loss of competition caused by the merger, depends upon the nature of the industry and the merging firms' positions in it, and the Agencies may accordingly use a price increase that is larger or smaller than five percent. Where explicit or implicit prices for the firms' specific contribution to value can be identified with reasonable clarity, the Agencies may base the SSNIP on those prices.

> *Example 8:* In a merger between two oil pipelines, the SSNIP would be based on the price charged for transporting the oil, not on the price of the oil itself. If pipelines buy the oil at one end and sell it at the other, the price charged for transporting the oil is implicit, equal to the difference between the price paid for oil at the input end and the price charged for oil at the output end. The relevant product sold by the pipelines is better described as "pipeline transportation of oil from point A to point B" than as "oil at point B."

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[5] Market definition for the evaluation of non-merger antitrust concerns such as monopolization or facilitating practices will differ in this respect if the effects resulting from the conduct of concern are already occurring at the time of evaluation.

Example 9: In a merger between two firms that install computers purchased from third parties, the SSNIP would be based on their fees, not on the price of installed computers. If these firms purchase the computers and charge their customers one package price, the implicit installation fee is equal to the package charge to customers less the price of the computers.

Example 10: In Example 9, suppose that the prices paid by the merging firms to purchase computers are opaque, but account for at least ninety-five percent of the prices they charge for installed computers, with profits or implicit fees making up five percent of those prices at most. A five percent SSNIP on the total price paid by customers would at least double those fees or profits. Even if that would be unprofitable for a hypothetical monopolist, a significant increase in fees might well be profitable. If the SSNIP is based on the total price paid by customers, a lower percentage will be used.

4.1.3 Implementing the Hypothetical Monopolist Test

The hypothetical monopolist's incentive to raise prices depends both on the extent to which customers would likely substitute away from the products in the candidate market in response to such a price increase and on the profit margins earned on those products. The profit margin on incremental units is the difference between price and incremental cost on those units. The Agencies often estimate incremental costs, for example using merging parties' documents or data the merging parties use to make business decisions. Incremental cost is measured over the change in output that would be caused by the price increase under consideration.

In considering customers' likely responses to higher prices, the Agencies take into account any reasonably available and reliable evidence, including, but not limited to:

- how customers have shifted purchases in the past in response to relative changes in price or other terms and conditions;
- information from buyers, including surveys, concerning how they would respond to price changes;
- the conduct of industry participants, notably:
  - sellers' business decisions or business documents indicating sellers' informed beliefs concerning how customers would substitute among products in response to relative changes in price;
  - industry participants' behavior in tracking and responding to price changes by some or all rivals;
- objective information about product characteristics and the costs and delays of switching products, especially switching from products in the candidate market to products outside the candidate market;
- the percentage of sales lost by one product in the candidate market, when its price alone rises, that is recaptured by other products in the candidate market, with a higher recapture percentage making a price increase more profitable for the hypothetical monopolist;
- evidence from other industry participants, such as sellers of complementary products;

- legal or regulatory requirements; and
- the influence of downstream competition faced by customers in their output markets.

When the necessary data are available, the Agencies also may consider a "critical loss analysis" to assess the extent to which it corroborates inferences drawn from the evidence noted above. Critical loss analysis asks whether imposing at least a SSNIP on one or more products in a candidate market would raise or lower the hypothetical monopolist's profits. While this "breakeven" analysis differs from the profit-maximizing analysis called for by the hypothetical monopolist test in Section 4.1.1, merging parties sometimes present this type of analysis to the Agencies. A price increase raises profits on sales made at the higher price, but this will be offset to the extent customers substitute away from products in the candidate market. Critical loss analysis compares the magnitude of these two offsetting effects resulting from the price increase. The "critical loss" is defined as the number of lost unit sales that would leave profits unchanged. The "predicted loss" is defined as the number of unit sales that the hypothetical monopolist is predicted to lose due to the price increase. The price increase raises the hypothetical monopolist's profits if the predicted loss is less than the critical loss.

The Agencies consider all of the evidence of customer substitution noted above in assessing the predicted loss. The Agencies require that estimates of the predicted loss be consistent with that evidence, including the pre-merger margins of products in the candidate market used to calculate the critical loss. Unless the firms are engaging in coordinated interaction (see Section 7), high pre-merger margins normally indicate that each firm's product individually faces demand that is not highly sensitive to price.[6] Higher pre-merger margins thus indicate a smaller predicted loss as well as a smaller critical loss. The higher the pre-merger margin, the smaller the recapture percentage necessary for the candidate market to satisfy the hypothetical monopolist test.

Even when the evidence necessary to perform the hypothetical monopolist test quantitatively is not available, the conceptual framework of the test provides a useful methodological tool for gathering and analyzing evidence pertinent to customer substitution and to market definition. The Agencies follow the hypothetical monopolist test to the extent possible given the available evidence, bearing in mind that the ultimate goal of market definition is to help determine whether the merger may substantially lessen competition.

4.1.4 Product Market Definition with Targeted Customers

If a hypothetical monopolist could profitably target a subset of customers for price increases, the Agencies may identify relevant markets defined around those targeted customers, to whom a hypothetical monopolist would profitably and separately impose at least a SSNIP. Markets to serve targeted customers are also known as price discrimination markets. In practice, the Agencies identify price discrimination markets only where they believe there is a realistic prospect of an adverse competitive effect on a group of targeted customers.

> *Example 11:* Glass containers have many uses. In response to a price increase for glass containers, some users would substitute substantially to plastic or metal containers, but baby food manufacturers would not. If a

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[6] While margins are important for implementing the hypothetical monopolist test, high margins are not in themselves of antitrust concern.

hypothetical monopolist could price separately and limit arbitrage, baby food manufacturers would be vulnerable to a targeted increase in the price of glass containers. The Agencies could define a distinct market for glass containers used to package baby food.

The Agencies also often consider markets for targeted customers when prices are individually negotiated and suppliers have information about customers that would allow a hypothetical monopolist to identify customers that are likely to pay a higher price for the relevant product. If prices are negotiated individually with customers, the hypothetical monopolist test may suggest relevant markets that are as narrow as individual customers (see also Section 6.2 on bargaining and auctions). Nonetheless, the Agencies often define markets for groups of targeted customers, i.e., by type of customer, rather than by individual customer. By so doing, the Agencies are able to rely on aggregated market shares that can be more helpful in predicting the competitive effects of the merger.

4.2 Geographic Market Definition

The arena of competition affected by the merger may be geographically bounded if geography limits some customers' willingness or ability to substitute to some products, or some suppliers' willingness or ability to serve some customers. Both supplier and customer locations can affect this. The Agencies apply the principles of market definition described here and in Section 4.1 to define a relevant market with a geographic dimension as well as a product dimension.

The scope of geographic markets often depends on transportation costs. Other factors such as language, regulation, tariff and non-tariff trade barriers, custom and familiarity, reputation, and service availability may impede long-distance or international transactions. The competitive significance of foreign firms may be assessed at various exchange rates, especially if exchange rates have fluctuated in the recent past.

In the absence of price discrimination based on customer location, the Agencies normally define geographic markets based on the locations of suppliers, as explained in subsection 4.2.1. In other cases, notably if price discrimination based on customer location is feasible as is often the case when delivered pricing is commonly used in the industry, the Agencies may define geographic markets based on the locations of customers, as explained in subsection 4.2.2.

4.2.1 Geographic Markets Based on the Locations of Suppliers

Geographic markets based on the locations of suppliers encompass the region from which sales are made. Geographic markets of this type often apply when customers receive goods or services at suppliers' locations. Competitors in the market are firms with relevant production, sales, or service facilities in that region. Some customers who buy from these firms may be located outside the boundaries of the geographic market.

The hypothetical monopolist test requires that a hypothetical profit-maximizing firm that was the only present or future producer of the relevant product(s) located in the region would impose at least a SSNIP from at least one location, including at least one location of one of the merging firms. In this exercise the terms of sale for all products produced elsewhere are held constant. A single firm may operate in a number of different geographic markets, even for a single product.

Example 12: The merging parties both have manufacturing plants in City X. The relevant product is expensive to transport and suppliers price their products for pickup at their locations. Rival plants are some distance away in City Y. A hypothetical monopolist controlling all plants in City X could profitably impose a SSNIP at these plants. Competition from more distant plants would not defeat the price increase because supplies coming from more distant plants require expensive transportation. The relevant geographic market is defined around the plants in City X.

When the geographic market is defined based on supplier locations, sales made by suppliers located in the geographic market are counted, regardless of the location of the customer making the purchase.

In considering likely reactions of customers to price increases for the relevant product(s) imposed in a candidate geographic market, the Agencies consider any reasonably available and reliable evidence, including:

- how customers have shifted purchases in the past between different geographic locations in response to relative changes in price or other terms and conditions;
- the cost and difficulty of transporting the product (or the cost and difficulty of a customer traveling to a seller's location), in relation to its price;
- whether suppliers need a presence near customers to provide service or support;
- evidence on whether sellers base business decisions on the prospect of customers switching between geographic locations in response to relative changes in price or other competitive variables;
- the costs and delays of switching from suppliers in the candidate geographic market to suppliers outside the candidate geographic market; and
- the influence of downstream competition faced by customers in their output markets.

4.2.2 Geographic Markets Based on the Locations of Customers

When the hypothetical monopolist could discriminate based on customer location, the Agencies may define geographic markets based on the locations of targeted customers.[7] Geographic markets of this type often apply when suppliers deliver their products or services to customers' locations. Geographic markets of this type encompass the region into which sales are made. Competitors in the market are firms that sell to customers in the specified region. Some suppliers that sell into the relevant market may be located outside the boundaries of the geographic market.

The hypothetical monopolist test requires that a hypothetical profit-maximizing firm that was the only present or future seller of the relevant product(s) to customers in the region would impose at least a SSNIP on some customers in that region. A region forms a relevant geographic market if this price increase would not be defeated by substitution away from the relevant product or by arbitrage,

[7] For customers operating in multiple locations, only those customer locations within the targeted zone are included in the market.

e.g., customers in the region travelling outside it to purchase the relevant product. In this exercise, the terms of sale for products sold to all customers outside the region are held constant.

> *Example 13:* Customers require local sales and support. Suppliers have sales and service operations in many geographic areas and can discriminate based on customer location. The geographic market can be defined around the locations of customers.

> *Example 14:* Each merging firm has a single manufacturing plant and delivers the relevant product to customers in City X and in City Y. The relevant product is expensive to transport. The merging firms' plants are by far the closest to City X, but no closer to City Y than are numerous rival plants. This fact pattern suggests that customers in City X may be harmed by the merger even if customers in City Y are not. For that reason, the Agencies consider a relevant geographic market defined around customers in City X. Such a market could be defined even if the region around the merging firms' plants would not be a relevant geographic market defined based on the location of sellers because a hypothetical monopolist controlling all plants in that region would find a SSNIP imposed on all of its customers unprofitable due to the loss of sales to customers in City Y.

When the geographic market is defined based on customer locations, sales made to those customers are counted, regardless of the location of the supplier making those sales.

> *Example 15:* Customers in the United States must use products approved by U.S. regulators. Foreign customers use products not approved by U.S. regulators. The relevant product market consists of products approved by U.S. regulators. The geographic market is defined around U.S. customers. Any sales made to U.S. customers by foreign suppliers are included in the market, and those foreign suppliers are participants in the U.S. market even though located outside it.

5. Market Participants, Market Shares, and Market Concentration

The Agencies normally consider measures of market shares and market concentration as part of their evaluation of competitive effects. The Agencies evaluate market shares and concentration in conjunction with other reasonably available and reliable evidence for the ultimate purpose of determining whether a merger may substantially lessen competition.

Market shares can directly influence firms' competitive incentives. For example, if a price reduction to gain new customers would also apply to a firm's existing customers, a firm with a large market share may be more reluctant to implement a price reduction than one with a small share. Likewise, a firm with a large market share may not feel pressure to reduce price even if a smaller rival does. Market shares also can reflect firms' capabilities. For example, a firm with a large market share may be able to expand output rapidly by a larger absolute amount than can a small firm. Similarly, a large market share tends to indicate low costs, an attractive product, or both.

5.1 Market Participants

All firms that currently earn revenues in the relevant market are considered market participants. Vertically integrated firms are also included to the extent that their inclusion accurately reflects their competitive significance. Firms not currently earning revenues in the relevant market, but that have committed to entering the market in the near future, are also considered market participants.

Firms that are not current producers in a relevant market, but that would very likely provide rapid supply responses with direct competitive impact in the event of a SSNIP, without incurring

significant sunk costs, are also considered market participants. These firms are termed "rapid entrants." Sunk costs are entry or exit costs that cannot be recovered outside the relevant market. Entry that would take place more slowly in response to adverse competitive effects, or that requires firms to incur significant sunk costs, is considered in Section 9.

Firms that produce the relevant product but do not sell it in the relevant geographic market may be rapid entrants. Other things equal, such firms are most likely to be rapid entrants if they are close to the geographic market.

> *Example 16:* Farm A grows tomatoes halfway between Cities X and Y. Currently, it ships its tomatoes to City X because prices there are two percent higher. Previously it has varied the destination of its shipments in response to small price variations. Farm A would likely be a rapid entrant participant in a market for tomatoes in City Y.
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> *Example 17:* Firm B has bid multiple times to supply milk to School District S, and actually supplies milk to schools in some adjacent areas. It has never won a bid in School District S, but is well qualified to serve that district and has often nearly won. Firm B would be counted as a rapid entrant in a market for school milk in School District S.

More generally, if the relevant market is defined around targeted customers, firms that produce relevant products but do not sell them to those customers may be rapid entrants if they can easily and rapidly begin selling to the targeted customers.

Firms that clearly possess the necessary assets to supply into the relevant market rapidly may also be rapid entrants. In markets for relatively homogeneous goods where a supplier's ability to compete depends predominantly on its costs and its capacity, and not on other factors such as experience or reputation in the relevant market, a supplier with efficient idle capacity, or readily available "swing" capacity currently used in adjacent markets that can easily and profitably be shifted to serve the relevant market, may be a rapid entrant.[8] However, idle capacity may be inefficient, and capacity used in adjacent markets may not be available, so a firm's possession of idle or swing capacity alone does not make that firm a rapid entrant.

5.2 Market Shares

The Agencies normally calculate market shares for all firms that currently produce products in the relevant market, subject to the availability of data. The Agencies also calculate market shares for other market participants if this can be done to reliably reflect their competitive significance.

Market concentration and market share data are normally based on historical evidence. However, recent or ongoing changes in market conditions may indicate that the current market share of a particular firm either understates or overstates the firm's future competitive significance. The Agencies consider reasonably predictable effects of recent or ongoing changes in market conditions when calculating and interpreting market share data. For example, if a new technology that is important to long-term competitive viability is available to other firms in the market, but is not available to a particular firm, the Agencies may conclude that that firm's historical market share

[8] If this type of supply side substitution is nearly universal among the firms selling one or more of a group of products, the Agencies may use an aggregate description of markets for those products as a matter of convenience.

overstates its future competitive significance. The Agencies may project historical market shares into the foreseeable future when this can be done reliably.

The Agencies measure market shares based on the best available indicator of firms' future competitive significance in the relevant market. This may depend upon the type of competitive effect being considered, and on the availability of data. Typically, annual data are used, but where individual transactions are large and infrequent so annual data may be unrepresentative, the Agencies may measure market shares over a longer period of time.

In most contexts, the Agencies measure each firm's market share based on its actual or projected revenues in the relevant market. Revenues in the relevant market tend to be the best measure of attractiveness to customers, since they reflect the real-world ability of firms to surmount all of the obstacles necessary to offer products on terms and conditions that are attractive to customers. In cases where one unit of a low-priced product can substitute for one unit of a higher-priced product, unit sales may measure competitive significance better than revenues. For example, a new, much less expensive product may have great competitive significance if it substantially erodes the revenues earned by older, higher-priced products, even if it earns relatively few revenues. In cases where customers sign long-term contracts, face switching costs, or tend to re-evaluate their suppliers only occasionally, revenues earned from recently acquired customers may better reflect the competitive significance of suppliers than do total revenues.

In markets for homogeneous products, a firm's competitive significance may derive principally from its ability and incentive to rapidly expand production in the relevant market in response to a price increase or output reduction by others in that market. As a result, a firm's competitive significance may depend upon its level of readily available capacity to serve the relevant market if that capacity is efficient enough to make such expansion profitable. In such markets, capacities or reserves may better reflect the future competitive significance of suppliers than revenues, and the Agencies may calculate market shares using those measures. Market participants that are not current producers may then be assigned positive market shares, but only if a measure of their competitive significance properly comparable to that of current producers is available. When market shares are measured based on firms' readily available capacities, the Agencies do not include capacity that is committed or so profitably employed outside the relevant market, or so high-cost, that it would not likely be used to respond to a SSNIP in the relevant market.

> *Example 18:* The geographic market is defined around customers in the United States. Firm X produces the relevant product outside the United States, and most of its sales are made to customers outside the United States. In most contexts, Firm X's market share will be based on its sales to U.S. customers, not its total sales or total capacity. However, if the relevant product is homogeneous, and if Firm X would significantly expand sales to U.S. customers rapidly and without incurring significant sunk costs in response to a SSNIP, the Agencies may base Firm X's market share on its readily available capacity to serve U.S. customers.

When the Agencies define markets serving targeted customers, these same principles are used to measure market shares, as they apply to those customers. In most contexts, each firm's market share is based on its actual or projected revenues from the targeted customers. However, the Agencies may instead measure market shares based on revenues from a broader group of customers if doing so would more accurately reflect the competitive significance of different suppliers in the relevant market. Revenues earned from a broader group of customers may also be used when better data are thereby available.

5.3 Market Concentration

Market concentration is often one useful indicator of likely competitive effects of a merger. In evaluating market concentration, the Agencies consider both the post-merger level of market concentration and the change in concentration resulting from a merger. Market shares may not fully reflect the competitive significance of firms in the market or the impact of a merger. They are used in conjunction with other evidence of competitive effects. See Sections 6 and 7.

In analyzing mergers between an incumbent and a recent or potential entrant, to the extent the Agencies use the change in concentration to evaluate competitive effects, they will do so using projected market shares. A merger between an incumbent and a potential entrant can raise significant competitive concerns. The lessening of competition resulting from such a merger is more likely to be substantial, the larger is the market share of the incumbent, the greater is the competitive significance of the potential entrant, and the greater is the competitive threat posed by this potential entrant relative to others.

The Agencies give more weight to market concentration when market shares have been stable over time, especially in the face of historical changes in relative prices or costs. If a firm has retained its market share even after its price has increased relative to those of its rivals, that firm already faces limited competitive constraints, making it less likely that its remaining rivals will replace the competition lost if one of that firm's important rivals is eliminated due to a merger. By contrast, even a highly concentrated market can be very competitive if market shares fluctuate substantially over short periods of time in response to changes in competitive offerings. However, if competition by one of the merging firms has significantly contributed to these fluctuations, perhaps because it has acted as a maverick, the Agencies will consider whether the merger will enhance market power by combining that firm with one of its significant rivals.

The Agencies may measure market concentration using the number of significant competitors in the market. This measure is most useful when there is a gap in market share between significant competitors and smaller rivals or when it is difficult to measure revenues in the relevant market. The Agencies also may consider the combined market share of the merging firms as an indicator of the extent to which others in the market may not be able readily to replace competition between the merging firms that is lost through the merger.

The Agencies often calculate the Herfindahl-Hirschman Index ("HHI") of market concentration. The HHI is calculated by summing the squares of the individual firms' market shares,[9] and thus gives proportionately greater weight to the larger market shares. When using the HHI, the Agencies

[9] For example, a market consisting of four firms with market shares of thirty percent, thirty percent, twenty percent, and twenty percent has an HHI of 2600 ($30^2 + 30^2 + 20^2 + 20^2 = 2600$). The HHI ranges from 10,000 (in the case of a pure monopoly) to a number approaching zero (in the case of an atomistic market). Although it is desirable to include all firms in the calculation, lack of information about firms with small shares is not critical because such firms do not affect the HHI significantly.

consider both the post-merger level of the HHI and the increase in the HHI resulting from the merger. The increase in the HHI is equal to twice the product of the market shares of the merging firms.[10]

Based on their experience, the Agencies generally classify markets into three types:

- Unconcentrated Markets: HHI below 1500
- Moderately Concentrated Markets: HHI between 1500 and 2500
- Highly Concentrated Markets: HHI above 2500

The Agencies employ the following general standards for the relevant markets they have defined:

- *Small Change in Concentration:* Mergers involving an increase in the HHI of less than 100 points are unlikely to have adverse competitive effects and ordinarily require no further analysis.
- *Unconcentrated Markets:* Mergers resulting in unconcentrated markets are unlikely to have adverse competitive effects and ordinarily require no further analysis.
- *Moderately Concentrated Markets:* Mergers resulting in moderately concentrated markets that involve an increase in the HHI of more than 100 points potentially raise significant competitive concerns and often warrant scrutiny.
- *Highly Concentrated Markets:* Mergers resulting in highly concentrated markets that involve an increase in the HHI of between 100 points and 200 points potentially raise significant competitive concerns and often warrant scrutiny. Mergers resulting in highly concentrated markets that involve an increase in the HHI of more than 200 points will be presumed to be likely to enhance market power. The presumption may be rebutted by persuasive evidence showing that the merger is unlikely to enhance market power.

The purpose of these thresholds is not to provide a rigid screen to separate competitively benign mergers from anticompetitive ones, although high levels of concentration do raise concerns. Rather, they provide one way to identify some mergers unlikely to raise competitive concerns and some others for which it is particularly important to examine whether other competitive factors confirm, reinforce, or counteract the potentially harmful effects of increased concentration. The higher the post-merger HHI and the increase in the HHI, the greater are the Agencies' potential competitive concerns and the greater is the likelihood that the Agencies will request additional information to conduct their analysis.

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[10] For example, the merger of firms with shares of five percent and ten percent of the market would increase the HHI by 100 ($5 \times 10 \times 2 = 100$).

6. Unilateral Effects

The elimination of competition between two firms that results from their merger may alone constitute a substantial lessening of competition. Such unilateral effects are most apparent in a merger to monopoly in a relevant market, but are by no means limited to that case. Whether cognizable efficiencies resulting from the merger are likely to reduce or reverse adverse unilateral effects is addressed in Section 10.

Several common types of unilateral effects are discussed in this section. Section 6.1 discusses unilateral price effects in markets with differentiated products. Section 6.2 discusses unilateral effects in markets where sellers negotiate with buyers or prices are determined through auctions. Section 6.3 discusses unilateral effects relating to reductions in output or capacity in markets for relatively homogeneous products. Section 6.4 discusses unilateral effects arising from diminished innovation or reduced product variety. These effects do not exhaust the types of possible unilateral effects; for example, exclusionary unilateral effects also can arise.

A merger may result in different unilateral effects along different dimensions of competition. For example, a merger may increase prices in the short term but not raise longer-term concerns about innovation, either because rivals will provide sufficient innovation competition or because the merger will generate cognizable research and development efficiencies. See Section 10.

6.1 Pricing of Differentiated Products

In differentiated product industries, some products can be very close substitutes and compete strongly with each other, while other products are more distant substitutes and compete less strongly. For example, one high-end product may compete much more directly with another high-end product than with any low-end product.

A merger between firms selling differentiated products may diminish competition by enabling the merged firm to profit by unilaterally raising the price of one or both products above the pre-merger level. Some of the sales lost due to the price rise will merely be diverted to the product of the merger partner and, depending on relative margins, capturing such sales loss through merger may make the price increase profitable even though it would not have been profitable prior to the merger.

The extent of direct competition between the products sold by the merging parties is central to the evaluation of unilateral price effects. Unilateral price effects are greater, the more the buyers of products sold by one merging firm consider products sold by the other merging firm to be their next choice. The Agencies consider any reasonably available and reliable information to evaluate the extent of direct competition between the products sold by the merging firms. This includes documentary and testimonial evidence, win/loss reports and evidence from discount approval processes, customer switching patterns, and customer surveys. The types of evidence relied on often overlap substantially with the types of evidence of customer substitution relevant to the hypothetical monopolist test. See Section 4.1.1.

Substantial unilateral price elevation post-merger for a product formerly sold by one of the merging firms normally requires that a significant fraction of the customers purchasing that product view

products formerly sold by the other merging firm as their next-best choice. However, unless pre-merger margins between price and incremental cost are low, that significant fraction need not approach a majority. For this purpose, incremental cost is measured over the change in output that would be caused by the price change considered. A merger may produce significant unilateral effects for a given product even though many more sales are diverted to products sold by non-merging firms than to products previously sold by the merger partner.

> *Example 19:* In Example 5, the merged entity controlling Products A and B would raise prices ten percent, given the product offerings and prices of other firms. In that example, one-third of the sales lost by Product A when its price alone is raised are diverted to Product B. Further analysis is required to account for repositioning, entry, and efficiencies.

In some cases, the Agencies may seek to quantify the extent of direct competition between a product sold by one merging firm and a second product sold by the other merging firm by estimating the diversion ratio from the first product to the second product. The diversion ratio is the fraction of unit sales lost by the first product due to an increase in its price that would be diverted to the second product. Diversion ratios between products sold by one merging firm and products sold by the other merging firm can be very informative for assessing unilateral price effects, with higher diversion ratios indicating a greater likelihood of such effects. Diversion ratios between products sold by merging firms and those sold by non-merging firms have at most secondary predictive value.

Adverse unilateral price effects can arise when the merger gives the merged entity an incentive to raise the price of a product previously sold by one merging firm and thereby divert sales to products previously sold by the other merging firm, boosting the profits on the latter products. Taking as given other prices and product offerings, that boost to profits is equal to the value to the merged firm of the sales diverted to those products. The value of sales diverted to a product is equal to the number of units diverted to that product multiplied by the margin between price and incremental cost on that product. In some cases, where sufficient information is available, the Agencies assess the value of diverted sales, which can serve as an indicator of the upward pricing pressure on the first product resulting from the merger. Diagnosing unilateral price effects based on the value of diverted sales need not rely on market definition or the calculation of market shares and concentration. The Agencies rely much more on the value of diverted sales than on the level of the HHI for diagnosing unilateral price effects in markets with differentiated products. If the value of diverted sales is proportionately small, significant unilateral price effects are unlikely.[11]

Where sufficient data are available, the Agencies may construct economic models designed to quantify the unilateral price effects resulting from the merger. These models often include independent price responses by non-merging firms. They also can incorporate merger-specific efficiencies. These merger simulation methods need not rely on market definition. The Agencies do not treat merger simulation evidence as conclusive in itself, and they place more weight on whether their merger simulations consistently predict substantial price increases than on the precise prediction of any single simulation.

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[11] For this purpose, the value of diverted sales is measured in proportion to the lost revenues attributable to the reduction in unit sales resulting from the price increase. Those lost revenues equal the reduction in the number of units sold of that product multiplied by that product's price.

A merger is unlikely to generate substantial unilateral price increases if non-merging parties offer very close substitutes for the products offered by the merging firms. In some cases, non-merging firms may be able to reposition their products to offer close substitutes for the products offered by the merging firms. Repositioning is a supply-side response that is evaluated much like entry, with consideration given to timeliness, likelihood, and sufficiency. See Section 9. The Agencies consider whether repositioning would be sufficient to deter or counteract what otherwise would be significant anticompetitive unilateral effects from a differentiated products merger.

6.2 Bargaining and Auctions

In many industries, especially those involving intermediate goods and services, buyers and sellers negotiate to determine prices and other terms of trade. In that process, buyers commonly negotiate with more than one seller, and may play sellers off against one another. Some highly structured forms of such competition are known as auctions. Negotiations often combine aspects of an auction with aspects of one-on-one negotiation, although pure auctions are sometimes used in government procurement and elsewhere.

A merger between two competing sellers prevents buyers from playing those sellers off against each other in negotiations. This alone can significantly enhance the ability and incentive of the merged entity to obtain a result more favorable to it, and less favorable to the buyer, than the merging firms would have offered separately absent the merger. The Agencies analyze unilateral effects of this type using similar approaches to those described in Section 6.1.

Anticompetitive unilateral effects in these settings are likely in proportion to the frequency or probability with which, prior to the merger, one of the merging sellers had been the runner-up when the other won the business. These effects also are likely to be greater, the greater advantage the runner-up merging firm has over other suppliers in meeting customers' needs. These effects also tend to be greater, the more profitable were the pre-merger winning bids. All of these factors are likely to be small if there are many equally placed bidders.

The mechanisms of these anticompetitive unilateral effects, and the indicia of their likelihood, differ somewhat according to the bargaining practices used, the auction format, and the sellers' information about one another's costs and about buyers' preferences. For example, when the merging sellers are likely to know which buyers they are best and second best placed to serve, any anticompetitive unilateral effects are apt to be targeted at those buyers; when sellers are less well informed, such effects are more apt to be spread over a broader class of buyers.

6.3 Capacity and Output for Homogeneous Products

In markets involving relatively undifferentiated products, the Agencies may evaluate whether the merged firm will find it profitable unilaterally to suppress output and elevate the market price. A firm may leave capacity idle, refrain from building or obtaining capacity that would have been obtained absent the merger, or eliminate pre-existing production capabilities. A firm may also divert the use of capacity away from one relevant market and into another so as to raise the price in the former market. The competitive analyses of these alternative modes of output suppression may differ.

A unilateral output suppression strategy is more likely to be profitable when (1) the merged firm's market share is relatively high; (2) the share of the merged firm's output already committed for sale at prices unaffected by the output suppression is relatively low; (3) the margin on the suppressed output is relatively low; (4) the supply responses of rivals are relatively small; and (5) the market elasticity of demand is relatively low.

A merger may provide the merged firm a larger base of sales on which to benefit from the resulting price rise, or it may eliminate a competitor that otherwise could have expanded its output in response to the price rise.

> *Example 20:* Firms A and B both produce an industrial commodity and propose to merge. The demand for this commodity is insensitive to price. Firm A is the market leader. Firm B produces substantial output, but its operating margins are low because it operates high-cost plants. The other suppliers are operating very near capacity. The merged firm has an incentive to reduce output at the high-cost plants, perhaps shutting down some of that capacity, thus driving up the price it receives on the remainder of its output. The merger harms customers, notwithstanding that the merged firm shifts some output from high-cost plants to low-cost plants.

In some cases, a merger between a firm with a substantial share of the sales in the market and a firm with significant excess capacity to serve that market can make an output suppression strategy profitable.[12] This can occur even if the firm with the excess capacity has a relatively small share of sales, if that firm's ability to expand, and thus keep price from rising, has been making an output suppression strategy unprofitable for the firm with the larger market share.

6.4 Innovation and Product Variety

Competition often spurs firms to innovate. The Agencies may consider whether a merger is likely to diminish innovation competition by encouraging the merged firm to curtail its innovative efforts below the level that would prevail in the absence of the merger. That curtailment of innovation could take the form of reduced incentive to continue with an existing product-development effort or reduced incentive to initiate development of new products.

The first of these effects is most likely to occur if at least one of the merging firms is engaging in efforts to introduce new products that would capture substantial revenues from the other merging firm. The second, longer-run effect is most likely to occur if at least one of the merging firms has capabilities that are likely to lead it to develop new products in the future that would capture substantial revenues from the other merging firm. The Agencies therefore also consider whether a merger will diminish innovation competition by combining two of a very small number of firms with the strongest capabilities to successfully innovate in a specific direction.

The Agencies evaluate the extent to which successful innovation by one merging firm is likely to take sales from the other, and the extent to which post-merger incentives for future innovation will be lower than those that would prevail in the absence of the merger. The Agencies also consider whether the merger is likely to enable innovation that would not otherwise take place, by bringing together

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[12] Such a merger also can cause adverse coordinated effects, especially if the acquired firm with excess capacity was disrupting effective coordination.

complementary capabilities that cannot be otherwise combined or for some other merger-specific reason. See Section 10.

The Agencies also consider whether a merger is likely to give the merged firm an incentive to cease offering one of the relevant products sold by the merging parties. Reductions in variety following a merger may or may not be anticompetitive. Mergers can lead to the efficient consolidation of products when variety offers little in value to customers. In other cases, a merger may increase variety by encouraging the merged firm to reposition its products to be more differentiated from one another.

If the merged firm would withdraw a product that a significant number of customers strongly prefer to those products that would remain available, this can constitute a harm to customers over and above any effects on the price or quality of any given product. If there is evidence of such an effect, the Agencies may inquire whether the reduction in variety is largely due to a loss of competitive incentives attributable to the merger. An anticompetitive incentive to eliminate a product as a result of the merger is greater and more likely, the larger is the share of profits from that product coming at the expense of profits from products sold by the merger partner. Where a merger substantially reduces competition by bringing two close substitute products under common ownership, and one of those products is eliminated, the merger will often also lead to a price increase on the remaining product, but that is not a necessary condition for anticompetitive effect.

> *Example 21:* Firm A sells a high-end product at a premium price. Firm B sells a mid-range product at a lower price, serving customers who are more price sensitive. Several other firms have low-end products. Firms A and B together have a large share of the relevant market. Firm A proposes to acquire Firm B and discontinue Firm B's product. Firm A expects to retain most of Firm B's customers. Firm A may not find it profitable to raise the price of its high-end product after the merger, because doing so would reduce its ability to retain Firm B's more price-sensitive customers. The Agencies may conclude that the withdrawal of Firm B's product results from a loss of competition and materially harms customers.

7. Coordinated Effects

A merger may diminish competition by enabling or encouraging post-merger coordinated interaction among firms in the relevant market that harms customers. Coordinated interaction involves conduct by multiple firms that is profitable for each of them only as a result of the accommodating reactions of the others. These reactions can blunt a firm's incentive to offer customers better deals by undercutting the extent to which such a move would win business away from rivals. They also can enhance a firm's incentive to raise prices, by assuaging the fear that such a move would lose customers to rivals.

Coordinated interaction includes a range of conduct. Coordinated interaction can involve the explicit negotiation of a common understanding of how firms will compete or refrain from competing. Such conduct typically would itself violate the antitrust laws. Coordinated interaction also can involve a similar common understanding that is not explicitly negotiated but would be enforced by the detection and punishment of deviations that would undermine the coordinated interaction. Coordinated interaction alternatively can involve parallel accommodating conduct not pursuant to a prior understanding. Parallel accommodating conduct includes situations in which each rival's response to competitive moves made by others is individually rational, and not motivated by

retaliation or deterrence nor intended to sustain an agreed-upon market outcome, but nevertheless emboldens price increases and weakens competitive incentives to reduce prices or offer customers better terms. Coordinated interaction includes conduct not otherwise condemned by the antitrust laws.

The ability of rival firms to engage in coordinated conduct depends on the strength and predictability of rivals' responses to a price change or other competitive initiative. Under some circumstances, a merger can result in market concentration sufficient to strengthen such responses or enable multiple firms in the market to predict them more confidently, thereby affecting the competitive incentives of multiple firms in the market, not just the merged firm.

7.1 Impact of Merger on Coordinated Interaction

The Agencies examine whether a merger is likely to change the manner in which market participants interact, inducing substantially more coordinated interaction. The Agencies seek to identify how a merger might significantly weaken competitive incentives through an increase in the strength, extent, or likelihood of coordinated conduct. There are, however, numerous forms of coordination, and the risk that a merger will induce adverse coordinated effects may not be susceptible to quantification or detailed proof. Therefore, the Agencies evaluate the risk of coordinated effects using measures of market concentration (see Section 5) in conjunction with an assessment of whether a market is vulnerable to coordinated conduct. See Section 7.2. The analysis in Section 7.2 applies to moderately and highly concentrated markets, as unconcentrated markets are unlikely to be vulnerable to coordinated conduct.

Pursuant to the Clayton Act's incipiency standard, the Agencies may challenge mergers that in their judgment pose a real danger of harm through coordinated effects, even without specific evidence showing precisely how the coordination likely would take place. The Agencies are likely to challenge a merger if the following three conditions are all met: (1) the merger would significantly increase concentration and lead to a moderately or highly concentrated market; (2) that market shows signs of vulnerability to coordinated conduct (see Section 7.2); and (3) the Agencies have a credible basis on which to conclude that the merger may enhance that vulnerability. An acquisition eliminating a maverick firm (see Section 2.1.5) in a market vulnerable to coordinated conduct is likely to cause adverse coordinated effects.

7.2 Evidence a Market is Vulnerable to Coordinated Conduct

The Agencies presume that market conditions are conducive to coordinated interaction if firms representing a substantial share in the relevant market appear to have previously engaged in express collusion affecting the relevant market, unless competitive conditions in the market have since changed significantly. Previous express collusion in another geographic market will have the same weight if the salient characteristics of that other market at the time of the collusion are comparable to those in the relevant market. Failed previous attempts at collusion in the relevant market suggest that successful collusion was difficult pre-merger but not so difficult as to deter attempts, and a merger may tend to make success more likely. Previous collusion or attempted collusion in another product market may also be given substantial weight if the salient characteristics of that other market at the time of the collusion are closely comparable to those in the relevant market.

A market typically is more vulnerable to coordinated conduct if each competitively important firm's significant competitive initiatives can be promptly and confidently observed by that firm's rivals. This is more likely to be the case if the terms offered to customers are relatively transparent. Price transparency can be greater for relatively homogeneous products. Even if terms of dealing are not transparent, transparency regarding the identities of the firms serving particular customers can give rise to coordination, e.g., through customer or territorial allocation. Regular monitoring by suppliers of one another's prices or customers can indicate that the terms offered to customers are relatively transparent.

A market typically is more vulnerable to coordinated conduct if a firm's prospective competitive reward from attracting customers away from its rivals will be significantly diminished by likely responses of those rivals. This is more likely to be the case, the stronger and faster are the responses the firm anticipates from its rivals. The firm is more likely to anticipate strong responses if there are few significant competitors, if products in the relevant market are relatively homogeneous, if customers find it relatively easy to switch between suppliers, or if suppliers use meeting-competition clauses.

A firm is more likely to be deterred from making competitive initiatives by whatever responses occur if sales are small and frequent rather than via occasional large and long-term contracts or if relatively few customers will switch to it before rivals are able to respond. A firm is less likely to be deterred by whatever responses occur if the firm has little stake in the status quo. For example, a firm with a small market share that can quickly and dramatically expand, constrained neither by limits on production nor by customer reluctance to switch providers or to entrust business to a historically small provider, is unlikely to be deterred. Firms are also less likely to be deterred by whatever responses occur if competition in the relevant market is marked by leapfrogging technological innovation, so that responses by competitors leave the gains from successful innovation largely intact.

A market is more apt to be vulnerable to coordinated conduct if the firm initiating a price increase will lose relatively few customers after rivals respond to the increase. Similarly, a market is more apt to be vulnerable to coordinated conduct if a firm that first offers a lower price or improved product to customers will retain relatively few customers thus attracted away from its rivals after those rivals respond.

The Agencies regard coordinated interaction as more likely, the more the participants stand to gain from successful coordination. Coordination generally is more profitable, the lower is the market elasticity of demand.

Coordinated conduct can harm customers even if not all firms in the relevant market engage in the coordination, but significant harm normally is likely only if a substantial part of the market is subject to such conduct. The prospect of harm depends on the collective market power, in the relevant market, of firms whose incentives to compete are substantially weakened by coordinated conduct. This collective market power is greater, the lower is the market elasticity of demand. This collective market power is diminished by the presence of other market participants with small market shares and little stake in the outcome resulting from the coordinated conduct, if these firms can rapidly expand their sales in the relevant market.

Buyer characteristics and the nature of the procurement process can affect coordination. For example, sellers may have the incentive to bid aggressively for a large contract even if they expect strong responses by rivals. This is especially the case for sellers with small market shares, if they can realistically win such large contracts. In some cases, a large buyer may be able to strategically undermine coordinated conduct, at least as it pertains to that buyer's needs, by choosing to put up for bid a few large contracts rather than many smaller ones, and by making its procurement decisions opaque to suppliers.

8. Powerful Buyers

Powerful buyers are often able to negotiate favorable terms with their suppliers. Such terms may reflect the lower costs of serving these buyers, but they also can reflect price discrimination in their favor.

The Agencies consider the possibility that powerful buyers may constrain the ability of the merging parties to raise prices. This can occur, for example, if powerful buyers have the ability and incentive to vertically integrate upstream or sponsor entry, or if the conduct or presence of large buyers undermines coordinated effects. However, the Agencies do not presume that the presence of powerful buyers alone forestalls adverse competitive effects flowing from the merger. Even buyers that can negotiate favorable terms may be harmed by an increase in market power. The Agencies examine the choices available to powerful buyers and how those choices likely would change due to the merger. Normally, a merger that eliminates a supplier whose presence contributed significantly to a buyer's negotiating leverage will harm that buyer.

> *Example 22:* Customer C has been able to negotiate lower pre-merger prices than other customers by threatening to shift its large volume of purchases from one merging firm to the other. No other suppliers are as well placed to meet Customer C's needs for volume and reliability. The merger is likely to harm Customer C. In this situation, the Agencies could identify a price discrimination market consisting of Customer C and similarly placed customers. The merger threatens to end previous price discrimination in their favor.

Furthermore, even if some powerful buyers could protect themselves, the Agencies also consider whether market power can be exercised against other buyers.

> *Example 23:* In Example 22, if Customer C instead obtained the lower pre-merger prices based on a credible threat to supply its own needs, or to sponsor new entry, Customer C might not be harmed. However, even in this case, other customers may still be harmed.

9. Entry

The analysis of competitive effects in Sections 6 and 7 focuses on current participants in the relevant market. That analysis may also include some forms of entry. Firms that would rapidly and easily enter the market in response to a SSNIP are market participants and may be assigned market shares. See Sections 5.1 and 5.2. Firms that have, prior to the merger, committed to entering the market also will normally be treated as market participants. See Section 5.1. This section concerns entry or adjustments to pre-existing entry plans that are induced by the merger.

As part of their full assessment of competitive effects, the Agencies consider entry into the relevant market. The prospect of entry into the relevant market will alleviate concerns about adverse competitive effects only if such entry will deter or counteract any competitive effects of concern so the merger will not substantially harm customers.

The Agencies consider the actual history of entry into the relevant market and give substantial weight to this evidence. Lack of successful and effective entry in the face of non-transitory increases in the margins earned on products in the relevant market tends to suggest that successful entry is slow or difficult. Market values of incumbent firms greatly exceeding the replacement costs of their tangible assets may indicate that these firms have valuable intangible assets, which may be difficult or time consuming for an entrant to replicate.

A merger is not likely to enhance market power if entry into the market is so easy that the merged firm and its remaining rivals in the market, either unilaterally or collectively, could not profitably raise price or otherwise reduce competition compared to the level that would prevail in the absence of the merger. Entry is that easy if entry would be timely, likely, and sufficient in its magnitude, character, and scope to deter or counteract the competitive effects of concern.

The Agencies examine the timeliness, likelihood, and sufficiency of the entry efforts an entrant might practically employ. An entry effort is defined by the actions the firm must undertake to produce and sell in the market. Various elements of the entry effort will be considered. These elements can include: planning, design, and management; permitting, licensing, or other approvals; construction, debugging, and operation of production facilities; and promotion (including necessary introductory discounts), marketing, distribution, and satisfaction of customer testing and qualification requirements. Recent examples of entry, whether successful or unsuccessful, generally provide the starting point for identifying the elements of practical entry efforts. They also can be informative regarding the scale necessary for an entrant to be successful, the presence or absence of entry barriers, the factors that influence the timing of entry, the costs and risk associated with entry, and the sales opportunities realistically available to entrants.

If the assets necessary for an effective and profitable entry effort are widely available, the Agencies will not necessarily attempt to identify which firms might enter. Where an identifiable set of firms appears to have necessary assets that others lack, or to have particularly strong incentives to enter, the Agencies focus their entry analysis on those firms. Firms operating in adjacent or complementary markets, or large customers themselves, may be best placed to enter. However, the Agencies will not presume that a powerful firm in an adjacent market or a large customer will enter the relevant market unless there is reliable evidence supporting that conclusion.

In assessing whether entry will be timely, likely, and sufficient, the Agencies recognize that precise and detailed information may be difficult or impossible to obtain. The Agencies consider reasonably available and reliable evidence bearing on whether entry will satisfy the conditions of timeliness, likelihood, and sufficiency.

9.1 Timeliness

In order to deter the competitive effects of concern, entry must be rapid enough to make unprofitable overall the actions causing those effects and thus leading to entry, even though those actions would be profitable until entry takes effect.

Even if the prospect of entry does not deter the competitive effects of concern, post-merger entry may counteract them. This requires that the impact of entrants in the relevant market be rapid enough that customers are not significantly harmed by the merger, despite any anticompetitive harm that occurs prior to the entry.

The Agencies will not presume that an entrant can have a significant impact on prices before that entrant is ready to provide the relevant product to customers unless there is reliable evidence that anticipated future entry would have such an effect on prices.

9.2 Likelihood

Entry is likely if it would be profitable, accounting for the assets, capabilities, and capital needed and the risks involved, including the need for the entrant to incur costs that would not be recovered if the entrant later exits. Profitability depends upon (a) the output level the entrant is likely to obtain, accounting for the obstacles facing new entrants; (b) the price the entrant would likely obtain in the post-merger market, accounting for the impact of that entry itself on prices; and (c) the cost per unit the entrant would likely incur, which may depend upon the scale at which the entrant would operate.

9.3 Sufficiency

Even where timely and likely, entry may not be sufficient to deter or counteract the competitive effects of concern. For example, in a differentiated product industry, entry may be insufficient because the products offered by entrants are not close enough substitutes to the products offered by the merged firm to render a price increase by the merged firm unprofitable. Entry may also be insufficient due to constraints that limit entrants' competitive effectiveness, such as limitations on the capabilities of the firms best placed to enter or reputational barriers to rapid expansion by new entrants. Entry by a single firm that will replicate at least the scale and strength of one of the merging firms is sufficient. Entry by one or more firms operating at a smaller scale may be sufficient if such firms are not at a significant competitive disadvantage.

10. Efficiencies

Competition usually spurs firms to achieve efficiencies internally. Nevertheless, a primary benefit of mergers to the economy is their potential to generate significant efficiencies and thus enhance the merged firm's ability and incentive to compete, which may result in lower prices, improved quality, enhanced service, or new products. For example, merger-generated efficiencies may enhance competition by permitting two ineffective competitors to form a more effective competitor, e.g., by combining complementary assets. In a unilateral effects context, incremental cost reductions may reduce or reverse any increases in the merged firm's incentive to elevate price. Efficiencies also may lead to new or improved products, even if they do not immediately and directly affect price. In a

coordinated effects context, incremental cost reductions may make coordination less likely or effective by enhancing the incentive of a maverick to lower price or by creating a new maverick firm. Even when efficiencies generated through a merger enhance a firm's ability to compete, however, a merger may have other effects that may lessen competition and make the merger anticompetitive.

The Agencies credit only those efficiencies likely to be accomplished with the proposed merger and unlikely to be accomplished in the absence of either the proposed merger or another means having comparable anticompetitive effects. These are termed merger-specific efficiencies.[13] Only alternatives that are practical in the business situation faced by the merging firms are considered in making this determination. The Agencies do not insist upon a less restrictive alternative that is merely theoretical.

Efficiencies are difficult to verify and quantify, in part because much of the information relating to efficiencies is uniquely in the possession of the merging firms. Moreover, efficiencies projected reasonably and in good faith by the merging firms may not be realized. Therefore, it is incumbent upon the merging firms to substantiate efficiency claims so that the Agencies can verify by reasonable means the likelihood and magnitude of each asserted efficiency, how and when each would be achieved (and any costs of doing so), how each would enhance the merged firm's ability and incentive to compete, and why each would be merger-specific.

Efficiency claims will not be considered if they are vague, speculative, or otherwise cannot be verified by reasonable means. Projections of efficiencies may be viewed with skepticism, particularly when generated outside of the usual business planning process. By contrast, efficiency claims substantiated by analogous past experience are those most likely to be credited.

Cognizable efficiencies are merger-specific efficiencies that have been verified and do not arise from anticompetitive reductions in output or service. Cognizable efficiencies are assessed net of costs produced by the merger or incurred in achieving those efficiencies.

The Agencies will not challenge a merger if cognizable efficiencies are of a character and magnitude such that the merger is not likely to be anticompetitive in any relevant market.[14] To make the requisite determination, the Agencies consider whether cognizable efficiencies likely would be sufficient to reverse the merger's potential to harm customers in the relevant market, e.g., by preventing price

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[13] The Agencies will not deem efficiencies to be merger-specific if they could be attained by practical alternatives that mitigate competitive concerns, such as divestiture or licensing. If a merger affects not whether but only when an efficiency would be achieved, only the timing advantage is a merger-specific efficiency.

[14] The Agencies normally assess competition in each relevant market affected by a merger independently and normally will challenge the merger if it is likely to be anticompetitive in any relevant market. In some cases, however, the Agencies in their prosecutorial discretion will consider efficiencies not strictly in the relevant market, but so inextricably linked with it that a partial divestiture or other remedy could not feasibly eliminate the anticompetitive effect in the relevant market without sacrificing the efficiencies in the other market(s). Inextricably linked efficiencies are most likely to make a difference when they are great and the likely anticompetitive effect in the relevant market(s) is small so the merger is likely to benefit customers overall.

increases in that market.[15] In conducting this analysis, the Agencies will not simply compare the magnitude of the cognizable efficiencies with the magnitude of the likely harm to competition absent the efficiencies. The greater the potential adverse competitive effect of a merger, the greater must be the cognizable efficiencies, and the more they must be passed through to customers, for the Agencies to conclude that the merger will not have an anticompetitive effect in the relevant market. When the potential adverse competitive effect of a merger is likely to be particularly substantial, extraordinarily great cognizable efficiencies would be necessary to prevent the merger from being anticompetitive. In adhering to this approach, the Agencies are mindful that the antitrust laws give competition, not internal operational efficiency, primacy in protecting customers.

In the Agencies' experience, efficiencies are most likely to make a difference in merger analysis when the likely adverse competitive effects, absent the efficiencies, are not great. Efficiencies almost never justify a merger to monopoly or near-monopoly. Just as adverse competitive effects can arise along multiple dimensions of conduct, such as pricing and new product development, so too can efficiencies operate along multiple dimensions. Similarly, purported efficiency claims based on lower prices can be undermined if they rest on reductions in product quality or variety that customers value.

The Agencies have found that certain types of efficiencies are more likely to be cognizable and substantial than others. For example, efficiencies resulting from shifting production among facilities formerly owned separately, which enable the merging firms to reduce the incremental cost of production, are more likely to be susceptible to verification and are less likely to result from anticompetitive reductions in output. Other efficiencies, such as those relating to research and development, are potentially substantial but are generally less susceptible to verification and may be the result of anticompetitive output reductions. Yet others, such as those relating to procurement, management, or capital cost, are less likely to be merger-specific or substantial, or may not be cognizable for other reasons.

When evaluating the effects of a merger on innovation, the Agencies consider the ability of the merged firm to conduct research or development more effectively. Such efficiencies may spur innovation but not affect short-term pricing. The Agencies also consider the ability of the merged firm to appropriate a greater fraction of the benefits resulting from its innovations. Licensing and intellectual property conditions may be important to this enquiry, as they affect the ability of a firm to appropriate the benefits of its innovation. Research and development cost savings may be substantial and yet not be cognizable efficiencies because they are difficult to verify or result from anticompetitive reductions in innovative activities.

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[15] The Agencies normally give the most weight to the results of this analysis over the short term. The Agencies also may consider the effects of cognizable efficiencies with no short-term, direct effect on prices in the relevant market. Delayed benefits from efficiencies (due to delay in the achievement of, or the realization of customer benefits from, the efficiencies) will be given less weight because they are less proximate and more difficult to predict. Efficiencies relating to costs that are fixed in the short term are unlikely to benefit customers in the short term, but can benefit customers in the longer run, e.g., if they make new product introduction less expensive.

11. Failure and Exiting Assets

Notwithstanding the analysis above, a merger is not likely to enhance market power if imminent failure, as defined below, of one of the merging firms would cause the assets of that firm to exit the relevant market. This is an extreme instance of the more general circumstance in which the competitive significance of one of the merging firms is declining: the projected market share and significance of the exiting firm is zero. If the relevant assets would otherwise exit the market, customers are not worse off after the merger than they would have been had the merger been enjoined.

The Agencies do not normally credit claims that the assets of the failing firm would exit the relevant market unless all of the following circumstances are met: (1) the allegedly failing firm would be unable to meet its financial obligations in the near future; (2) it would not be able to reorganize successfully under Chapter 11 of the Bankruptcy Act; and (3) it has made unsuccessful good-faith efforts to elicit reasonable alternative offers that would keep its tangible and intangible assets in the relevant market and pose a less severe danger to competition than does the proposed merger.[16]

Similarly, a merger is unlikely to cause competitive harm if the risks to competition arise from the acquisition of a failing division. The Agencies do not normally credit claims that the assets of a division would exit the relevant market in the near future unless both of the following conditions are met: (1) applying cost allocation rules that reflect true economic costs, the division has a persistently negative cash flow on an operating basis, and such negative cash flow is not economically justified for the firm by benefits such as added sales in complementary markets or enhanced customer goodwill;[17] and (2) the owner of the failing division has made unsuccessful good-faith efforts to elicit reasonable alternative offers that would keep its tangible and intangible assets in the relevant market and pose a less severe danger to competition than does the proposed acquisition.

12. Mergers of Competing Buyers

Mergers of competing buyers can enhance market power on the buying side of the market, just as mergers of competing sellers can enhance market power on the selling side of the market. Buyer market power is sometimes called “monopsony power.”

To evaluate whether a merger is likely to enhance market power on the buying side of the market, the Agencies employ essentially the framework described above for evaluating whether a merger is likely to enhance market power on the selling side of the market. In defining relevant markets, the Agencies

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[16] Any offer to purchase the assets of the failing firm for a price above the liquidation value of those assets will be regarded as a reasonable alternative offer. Liquidation value is the highest value the assets could command for use outside the relevant market.

[17] Because the parent firm can allocate costs, revenues, and intra-company transactions among itself and its subsidiaries and divisions, the Agencies require evidence on these two points that is not solely based on management plans that could have been prepared for the purpose of demonstrating negative cash flow or the prospect of exit from the relevant market.

focus on the alternatives available to sellers in the face of a decrease in the price paid by a hypothetical monopsonist.

Market power on the buying side of the market is not a significant concern if suppliers have numerous attractive outlets for their goods or services. However, when that is not the case, the Agencies may conclude that the merger of competing buyers is likely to lessen competition in a manner harmful to sellers.

The Agencies distinguish between effects on sellers arising from a lessening of competition and effects arising in other ways. A merger that does not enhance market power on the buying side of the market can nevertheless lead to a reduction in prices paid by the merged firm, for example, by reducing transactions costs or allowing the merged firm to take advantage of volume-based discounts. Reduction in prices paid by the merging firms not arising from the enhancement of market power can be significant in the evaluation of efficiencies from a merger, as discussed in Section 10.

The Agencies do not view a short-run reduction in the quantity purchased as the only, or best, indicator of whether a merger enhances buyer market power. Nor do the Agencies evaluate the competitive effects of mergers between competing buyers strictly, or even primarily, on the basis of effects in the downstream markets in which the merging firms sell.

> *Example 24:* Merging Firms A and B are the only two buyers in the relevant geographic market for an agricultural product. Their merger will enhance buyer power and depress the price paid to farmers for this product, causing a transfer of wealth from farmers to the merged firm and inefficiently reducing supply. These effects can arise even if the merger will not lead to any increase in the price charged by the merged firm for its output.

13. Partial Acquisitions

In most horizontal mergers, two competitors come under common ownership and control, completely and permanently eliminating competition between them. This elimination of competition is a basic element of merger analysis. However, the statutory provisions referenced in Section 1 also apply to one firm's partial acquisition of a competitor. The Agencies therefore also review acquisitions of minority positions involving competing firms, even if such minority positions do not necessarily or completely eliminate competition between the parties to the transaction.

When the Agencies determine that a partial acquisition results in effective control of the target firm, or involves substantially all of the relevant assets of the target firm, they analyze the transaction much as they do a merger. Partial acquisitions that do not result in effective control may nevertheless present significant competitive concerns and may require a somewhat distinct analysis from that applied to full mergers or to acquisitions involving effective control. The details of the post-acquisition relationship between the parties, and how those details are likely to affect competition, can be important. While the Agencies will consider any way in which a partial acquisition may affect competition, they generally focus on three principal effects.

First, a partial acquisition can lessen competition by giving the acquiring firm the ability to influence the competitive conduct of the target firm. A voting interest in the target firm or specific governance rights, such as the right to appoint members to the board of directors, can permit such influence. Such

influence can lessen competition because the acquiring firm can use its influence to induce the target firm to compete less aggressively or to coordinate its conduct with that of the acquiring firm.

Second, a partial acquisition can lessen competition by reducing the incentive of the acquiring firm to compete. Acquiring a minority position in a rival might significantly blunt the incentive of the acquiring firm to compete aggressively because it shares in the losses thereby inflicted on that rival. This reduction in the incentive of the acquiring firm to compete arises even if cannot influence the conduct of the target firm. As compared with the unilateral competitive effect of a full merger, this effect is likely attenuated by the fact that the ownership is only partial.

Third, a partial acquisition can lessen competition by giving the acquiring firm access to non-public, competitively sensitive information from the target firm. Even absent any ability to influence the conduct of the target firm, access to competitively sensitive information can lead to adverse unilateral or coordinated effects. For example, it can enhance the ability of the two firms to coordinate their behavior, and make other accommodating responses faster and more targeted. The risk of coordinated effects is greater if the transaction also facilitates the flow of competitively sensitive information from the acquiring firm to the target firm.

Partial acquisitions, like mergers, vary greatly in their potential for anticompetitive effects. Accordingly, the specific facts of each case must be examined to assess the likelihood of harm to competition. While partial acquisitions usually do not enable many of the types of efficiencies associated with mergers, the Agencies consider whether a partial acquisition is likely to create cognizable efficiencies.

EXHIBIT 244

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF THE DISTRICT OF COLUMBIA

FEDERAL TRADE COMMISSION
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

Plaintiff,

v.

WARNER CHILCOTT HOLDINGS COMPANY III, LTD.
100 Enterprise Drive
Rockaway, N.J. 07866-2129

WARNER CHILCOTT CORPORATION
100 Enterprise Drive
Rockaway, N.J. 07866-2129

WARNER CHILCOTT (US) INC.
100 Enterprise Drive
Rockaway, N.J. 07866-2129

GALEN (CHEMICALS) LTD.
Unit 4 Burton Hall Pk.
Sandyford Industrial Estate
Foxrock, Ireland

and

BARR PHARMACEUTICALS, INC.
2 Quaker Road, P.O. Box 2900
Pomona, N.Y. 10970-0519

Defendants.

Civil Action No.

Complaint for Injunctive and Other Equitable Relief

Plaintiff, the Federal Trade Commission (FTC), by its designated attorneys, petitions this Court, pursuant to Section 13(b) of the Federal Trade Commission Act, 15 U.S.C. § 53(b)

(2005), for a permanent injunction against defendants Warner Chilcott Holdings Company III, Ltd., Warner Chilcott Corporation, Warner Chilcott (US) Inc., Galen (Chemicals) Ltd. (collectively "Warner Chilcott"), and Barr Pharmaceuticals, Inc. ("Barr"), to undo and prevent their unfair methods of competition in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, 15 U.S.C. § 45(a) (2005).

I. Introduction

1. This case involves a horizontal agreement not to compete between Warner Chilcott and Barr, two sellers of prescription drugs. Warner Chilcott sells Ovcon 35 ("Ovcon"), an oral contraceptive used to prevent pregnancy. Barr is the only company approved by the United States Food and Drug Administration ("FDA") to sell a generic version of Ovcon in competition with Warner Chilcott's branded Ovcon.

2. Prior to the challenged agreement, Barr planned to compete with Warner Chilcott by selling Barr's lower-priced generic Ovcon once Barr received FDA approval. Both Warner Chilcott and Barr predicted that entry of Barr's lower-priced generic into the market would reduce Warner Chilcott's higher-priced branded Ovcon's sales, by capturing approximately 50 percent of Ovcon's business in the first year alone.

3. To forestall this competitive threat and to protect its Ovcon sales, Warner Chilcott entered into an agreement with Barr preventing entry of Barr's generic Ovcon into the United States for five years. In exchange for Barr's agreement to keep its generic Ovcon off the market, Warner Chilcott paid Barr $20 million.

4. The effect of this anticompetitive agreement between Warner Chilcott and Barr has been to deprive purchasers of the choice of a lower-cost generic alternative to Warner Chilcott's higher-priced branded Ovcon.

II. Jurisdiction and Venue

5. This Court has subject matter jurisdiction over this action pursuant to 15 U.S.C. §§ 45(a) and 53(b) (2005), and 28 U.S.C. §§ 1331, 1337(a), and 1345 (2005).

6. This Court has personal jurisdiction over each defendant pursuant to 15 U.S.C. § 53(b) (2005), because each defendant has the requisite constitutional contacts with the United States of America, and because each defendant has engaged in an activity that violates provisions of law enforced by the Federal Trade Commission.

7. Venue in this district is proper under Section 13(b) of the FTC Act, 15 U.S.C. § 53(b) and 28 U.S.C. § 1391(b), (c), (d) (2005), because each defendant resides or transacts business in the District of Columbia, or is an alien.

8. The defendants' general business practices, and the unfair methods of competition alleged herein, are "in or affecting commerce" within the meaning of Section 5 of the FTC Act, 15 U.S.C. § 44 (2005).

9. Each defendant is, and at all times relevant herein has been, a corporation, as "corporation" is defined in Section 4 of the FTC Act, 15 U.S.C. § 44 (2005).

III. The Parties

10. Plaintiff FTC is an administrative agency of the United States government, established, organized, and existing pursuant to the FTC Act, 15 U.S.C. §§ 41 *et seq.* (2005), with its principal offices at 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. The FTC

is vested with authority and responsibility for enforcing, *inter alia*, Section 5 of the FTC Act, 15 U.S.C. § 45 (2005), and is authorized under Section 13(b) of the FTC Act, 15 U.S.C. § 53(b) (2005), to initiate court proceedings to enjoin violations of any law the FTC enforces.

11. Defendant Warner Chilcott Holdings Company III, Ltd. is a privately-owned, for-profit company organized, existing, and doing business under and by virtue of the laws of Bermuda, with its office and principal place of business located at 100 Enterprise Drive, Rockaway, New Jersey 07866-2129.

12. Warner Chilcott Holdings Company III, Ltd., through its direct and indirect subsidiaries, is engaged in the discovery, development, manufacturing, and distribution of pharmaceutical products in the United States, including Ovcon.

13. Defendant Warner Chilcott Corporation is a wholly-owned indirect subsidiary of Warner Chilcott Holdings Company III, Ltd. and is the direct 100% shareholder of Warner Chilcott (U.S.) Inc. Warner Chilcott Corporation is organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at 100 Enterprise Drive, Rockaway, New Jersey 07866-2129.

14. Defendant Warner Chilcott (U.S.) Inc., is a wholly-owned subsidiary of Warner Chilcott Corporation. Warner Chilcott (U.S.) Inc., is organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at 100 Enterprise Drive, Rockaway, New Jersey 07866-2129.

15. Galen (Chemicals) Ltd., is organized, existing, and doing business under and by virtue of the laws of the Republic of Ireland. Galen Chemicals is directly or indirectly owned or

controlled by Warner Chilcott Holdings Company III, Ltd. Galen Chemicals entered into the anticompetitive agreement that prevents Barr's generic Ovcon entry challenged herein.

16. In the twelve months ending September 30, 2004, Warner Chilcott had net revenues of approximately $490.2 million. During that same period, Warner Chilcott's gross profit margin on product net sales was approximately 89 percent.

17. Defendant Barr is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware. Barr's office and principal place of business is located at 2 Quaker Road, P.O. Box 2900, Pomona, New York 10970-0519.

18. Barr is engaged in the business of, among other things, developing, manufacturing, marketing, and distributing generic oral contraceptive products. In the twelve months ending June 30, 2004, Barr had net revenues of approximately $349 million and net income of approximately $123 million.

IV. Background

A. The Regulatory System Governing Pharmaceuticals in the United States

19. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act) and the Medicare Prescription Drug, Improvement and Modernization Act of 2003, codified at 21 U.S.C. § 355(j) and 35 U.S.C. § 271(e) (2005), establishes procedures designed to facilitate competition from lower-priced generic drugs, while maintaining incentives for pharmaceutical companies to invest in developing new drugs.

20. A company seeking FDA approval to market a new drug (i.e., a branded drug) must file a New Drug Application (NDA) demonstrating the safety and efficacy of its product. 21 U.S.C. § 355(b) (2005).

21. An "AB-rated" generic drug is one that the FDA has determined to be bioequivalent to a branded drug. A generic drug is considered bioequivalent to a branded drug if it contains the same active pharmaceutical ingredient as the branded drug, and if there is no significant difference in the formulation, quality, and effectiveness of the two drugs. *See* 21 U.S.C. § 355(j)(8)(B) (2005).

22. A company seeking to market an "AB-rated" generic version of a branded drug may file an Abbreviated New Drug Application (ANDA) with the FDA. 21 U.S.C. § 355(j) (2005).

23. FDA approval of an ANDA takes, on average, about 18 months, although the approval process can take two years or more.

B. The Consumer Benefits of Generic Drugs

24. Almost all states (and the District of Columbia) encourage generic competition through laws that allow pharmacists to dispense an AB-rated generic drug when presented with a prescription for its branded equivalent, unless a physician directs, or the patient requests, otherwise. These state laws facilitate substitution of the lower-priced AB-rated generic drugs for the higher-priced branded drugs.

25. Many third party payers of prescription drugs (e.g., health insurance plans, Medicaid programs) have adopted policies to encourage the substitution of AB-rated generic drugs for their branded counterparts, when an AB-rated generic is available.

26. As a result of these lower prices and the ease of substitution, many consumers routinely switch from a branded drug to an AB-rated generic drug upon its introduction. Consequently, AB-rated generic drugs, after their introduction, typically promptly capture a significant share of their branded counterparts' sales, causing a significant reduction of the branded drug's unit and dollar sales.

27. Competition from generic drugs generates large savings for consumers. A 1998 Congressional Budget Office Report estimates that in 1994 alone, purchasers saved $8-10 billion on prescriptions at retail pharmacies by purchasing generic drugs instead of the equivalent brand name drugs. A 2004 FDA study calculates that patients could reduce the daily costs of their medications by more than 50 percent by purchasing generic drugs when available.

C. Warner Chilcott's Ovcon Oral Contraceptive

28. Ovcon was originally approved by the FDA in 1976, and it is not subject to patent protection. Warner Chilcott acquired Ovcon from Bristol-Myers Squibb Company on January 26, 2000. As part of the acquisition, Bristol-Myers Squibb Company agreed to supply (and has supplied) Ovcon to Warner Chilcott.

29. Ovcon's net dollar sales have more than doubled since 2000, even as Warner Chilcott has raised Ovcon's price.

30. Ovcon is, and has been, one of Warner Chilcott's highest revenue-producing products.

31. Warner Chilcott sells Ovcon at a price substantially above Warner Chilcott's cost of acquiring the product.

32. Ovcon is highly profitable for Warner Chilcott. For the twelve months ending September 30, 2004, Warner Chilcott's net sales of Ovcon were approximately $71.5 million.

D. The Threat of Barr's Generic Ovcon Entry to Warner Chilcott

33. In September 2001, Barr filed an ANDA with the FDA for approval to manufacture and sell an AB-rated generic version of Ovcon.

34. In January 2003, Barr publicly announced its intention to market generic Ovcon by the end of that year.

35. Barr planned to price generic Ovcon at approximately 30 percent less than the price that Warner Chilcott charges for branded Ovcon.

36. Barr projected that its generic Ovcon would capture approximately 50 percent of Warner Chilcott's branded Ovcon sales within the first year of introduction.

37. Warner Chilcott expected that Barr would price its generic Ovcon at approximately 30 percent less than the price Warner Chilcott charges for branded Ovcon.

38. Warner Chilcott projected that generic Ovcon would capture at least 50 percent of Ovcon's new prescriptions within the first year of introduction. Warner Chilcott calculated that, as a result of these lost prescriptions, its net revenues from the sale of branded Ovcon would decline by at least $100 million over a three year period.

39. Warner Chilcott had planned to protect its Ovcon revenues from generic competition by introducing a chewable form of the product (Ovcon Chewable) before generic Ovcon entry occurred. Warner Chilcott's strategy was to convert its Ovcon customers to Ovcon Chewable and to stop selling Ovcon. Prescriptions for Ovcon Chewable could not be filled at the

pharmacy with a generic Ovcon product (absent express approval of the patient's physician), because any generic version of Ovcon would not be AB-rated to Ovcon Chewable.

40. By mid-2003, however, Warner Chilcott's "switch" strategy to protect its Ovcon revenues – by converting customers to Ovcon Chewable before generic Ovcon entry – was in jeopardy. Barr's generic Ovcon entry appeared imminent, and Ovcon Chewable had not obtained FDA approval.

41. In May 2003, Warner Chilcott's chief financial officer warned the company's Board of Directors that generic Ovcon entry was the "biggest risk to the company."

V. The Defendants' Horizontal Agreement Not to Compete

42. By the summer of 2003, Warner Chilcott believed that Barr's generic Ovcon entry could occur as early as September of that year.

43. In August 2003, Warner Chilcott and Barr discussed a possible business arrangement under which Barr would agree to refrain from competing in the United States with its generic Ovcon product.

44. On September 10, 2003, Warner Chilcott and Barr executed a letter of intent. According to the letter of intent, Warner Chilcott would pay Barr $20 million and Barr would not compete in the United States for five years with its generic Ovcon product when Barr received final FDA approval. Instead of entering and competing, Barr would agree to be available as a second supplier of Ovcon to Warner Chilcott if Warner Chilcott so requested.

45. In February 2004, FTC staff notified Warner Chilcott and Barr that it intended to investigate the non-compete agreement outlined in the defendants' letter of intent because of its potential to significantly reduce competition by eliminating the only generic alternative to Ovcon.

46. On March 24, 2004, the defendants signed their Final Agreement implementing the letter of intent. Warner Chilcott paid Barr $1 million upon signing the Final Agreement.

47. Under the Final Agreement, within 45 days after the FDA approved Barr's generic Ovcon ANDA, Warner Chilcott could elect to pay the remaining $19 million to secure Barr's agreement to refrain from marketing generic Ovcon in the United States, either by itself or through a licensee, for five years. The Final Agreement referred to this arrangement as Warner Chilcott's option to an exclusive license to Barr's ANDA for generic Ovcon.

48. In addition, the Final Agreement gave Warner Chilcott the ability to purchase Ovcon supply from Barr, pursuant to specified payment terms. The ability to purchase supply from Barr would arise, however, only after Barr received final FDA approval for its generic Ovcon. Both Warner Chilcott and Barr understood that if, upon receiving FDA approval, Barr went ahead and entered the market with its generic Ovcon product, Warner Chilcott's Ovcon supply needs would immediately be drastically reduced.

VI. The Defendants Carry Out Their Horizontal Agreement Not to Compete

49. On April 22, 2004, the FDA approved Barr's ANDA to produce and market generic Ovcon.

50. Upon receiving final FDA approval for its generic Ovcon ANDA, Barr had the desire, intent, and capability to market generic Ovcon in the United States.

51. On April 23, 2004, Barr publicly announced its intention to market generic Ovcon if Warner Chilcott chose not to exercise its exclusive license option.

52. On May 6, 2004, Warner Chilcott exercised the exclusive license option under the Final Agreement by paying Barr $19 million.

53. Warner Chilcott did not begin purchasing Ovcon supply from Barr at that time, but instead continued to purchase Ovcon supply solely from Bristol-Myers Squibb Co., until about May 2005.

54. Under the terms of the Final Agreement, Barr cannot sell generic Ovcon in the United States for five years, or until approximately May 2009. Absent its agreement not to compete with Warner Chilcott, Barr would have started selling generic Ovcon shortly after receiving final FDA approval in April 2004.

55. Entry of Barr's generic Ovcon into the United States would have quickly and significantly reduced the sales of Warner Chilcott's branded Ovcon, and led to a significant reduction in the average price purchasers paid for Ovcon products.

56. Barr has abided by its agreement not to sell generic Ovcon in the United States.

57. As of the date of this complaint, Barr remains the only company that has received approval from the FDA to make an AB-rated generic version of Ovcon.

VII. The Defendants' Agreement Not to Compete Harms Competition and Consumer Welfare

58. Entry of Barr's generic Ovcon would give consumers the choice between branded Ovcon and Barr's lower-priced generic Ovcon.

59. Had Barr entered the United States with its generic Ovcon, many consumers would have purchased Barr's lower-priced, therapeutically-equivalent generic drug instead of Warner Chilcott's higher-priced branded drug.

60. The agreement not to compete, which prevents Barr's generic Ovcon entry for five years, deprives United States consumers of the choice of purchasing Barr's lower-priced generic Ovcon instead of Warner Chilcott's higher-priced branded Ovcon.

61. Entry of Barr's generic Ovcon would benefit consumers.

VIII. Violation of Section 5 of the FTC Act

62. The defendants' horizontal agreement not to compete, which prevents Barr's AB-rated generic Ovcon entry for five years, on its face eliminates competition and has no plausible procompetitive justification. The agreement, therefore, is a naked restraint of trade.

63. By preventing entry of Barr's generic Ovcon into the United States for five years, the agreement not to compete limits consumer choice and impedes the ordinary give and take of the marketplace. The likely competitive harm from defendants' agreement not to compete is readily apparent from the nature of the restraint itself.

64. The defendants' horizontal agreement not to compete, which prevents entry of Barr's generic Ovcon for five years, is not ancillary to any procompetitive undertaking.

a. Preventing competition from Barr's generic Ovcon for five years is not subordinate to any procompetitive undertaking, but rather is the primary purpose of defendants' anticompetitive agreement.

b. Preventing competition from Barr's generic Ovcon for five years is not reasonably necessary to accomplish any undertaking that enhances competition.

65. The defendants could have achieved any purported procompetitive benefits of their agreement through means appreciably less restrictive of competition than preventing competition from Barr's generic Ovcon for five years.

66. Even under a broader inquiry, the agreement not to compete is anticompetitive. The purpose and effect of this agreement is to prevent Barr – which has the only FDA-approved generic Ovcon product – from offering consumers a lower-priced, therapeutically equivalent alternative to Warner Chilcott's higher-priced branded Ovcon. Consequently, as a result of defendants' agreement not to compete, an agreement that lacks any countervailing efficiency-enhancing justification, many purchasers – including consumers, insurers, pharmacies, wholesalers, government agencies, managed care organizations, and others – are paying higher prices in the market for Ovcon and its AB-rated generic equivalents than would otherwise prevail absent the agreement not to compete.

67. By entering into this illegal horizontal agreement not to compete, defendants Warner Chilcott and Barr have engaged, and are engaging, in unfair methods of competition in or affecting commerce, in violation of Section 5 of the FTC Act. 15 U.S.C. § 45 (2005).

IX. The Court's Power to Grant Relief

68. Section 13(b) of the FTC Act empowers this Court to issue a permanent injunction against violations of the FTC Act and, in the exercise of its equitable jurisdiction, to order ancillary equitable relief to remedy the injury caused by defendants' violations.

X. Prayer for Relief

WHEREFORE, the FTC requests that this Court, as authorized by 15 U.S.C. § 53(b) (2005), 15 U.S.C. § 26 (2005), and pursuant to its own equitable powers, enter final judgment against defendants, declaring, ordering, and adjudging:

1. That the agreement between defendants Warner Chilcott and Barr preventing competition from Barr's generic Ovcon drug product for five years violates Section 5(a) of the FTC Act, 15 U.S.C. § 45(a) (2005);

2. That defendants Warner Chilcott and Barr are permanently enjoined from maintaining or enforcing their agreement not to compete, which prevents competition from Barr's generic Ovcon drug product, and from engaging in similar and related conduct; and

3. That the Court grant such other equitable relief as the Court finds necessary to redress and prevent recurrence of defendants' violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), as alleged herein.

RESPECTFULLY SUBMITTED,

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Dated: November 7, 2005

EXHIBIT 245

IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law - Hovenkamp, Janis, Lemley and Leslie, § 15.3, Private Efforts to Manipulate Regulatory Frameworks as Antitrust Violations

Last Updated: 11/2013

15.3a. Collective Action; Section 1 Liability

In this section, we consider agreements and conspiracies that exist in the context of regulatory gaming. Section 15.3a1 discusses exclusionary settlements of pharmaceutical patent litigation against the backdrop of the Hatch-Waxman regulatory framework. Section 15.3a2 discusses settlements or other agreements that authorize generic entry.

15.3a1. Entry-restrictive Agreements; Exclusion or “Reverse” Payments

Insofar as antitrust is concerned, among the most problematic settlement agreements are those in which the infringement plaintiff pays the infringement defendant for the latter's abandonment of the market (what we call in this book an “exclusion payment”). [78] To illustrate, suppose that a widget patentee observes incipient competition from a rival producer and files an infringement action. This lawsuit could be settled by (1) the infringement defendant's purchase of an exclusive or nonexclusive license from the patentee, followed by the defendant's production under the license; or (2) the infringement plaintiff's purchase of an agreement from the defendant that it abandon its entry plans. Alternative (1) brings a new rival into the market. It can facilitate competitive production, depending on whether the license is price- or quantity-restricted. It can also encourage further innovation in the market by giving two companies an incentive to improve on the widget. By contrast, alternative (2) keeps the rival out of the market and induces it to drop its suit in exchange for a payment. Thus, there are competitive reasons to favor inclusive rather than exclusive settlements.

In a perfectly functioning market without transaction costs, a monopoly producer would be indifferent between producing everything itself and simply “licensing” another to make part of its production. The license fee would be the monopoly markup, output would remain at the monopoly level as it would in any perfect cartel agreement, and the monopolist would earn the same profits, although part of them would be paid as license fees rather than as markup on goods that it produced.

If all parties were completely certain that a patent was valid and infringed, a patentee would have precisely the same set of incentives. It would either produce all output under the patent itself, or else it would license some output to a rival, earning the monopoly profits as royalties. [79] Assuming zero transaction costs, however, a firm in that position would have no incentive whatsoever to pay another firm to stay out of the market. It could exclude without paying anything at all. In fact, a large exclusion payment to an infringement defendant might simply signal that the patent is invalid or unenforceable, spurring entry by other rivals. By contrast, in the Hatch-Waxman situation we discuss in this section, exclusion payments may have been attractive to both parties because of the unusual opportunity that Hatch-Waxman presented: When the would-be first generic entrant declines to enter the market (in exchange for an exclusion payment), until 2004 subsequent generic entrants were precluded from entering the market at all until after the 180-day generic exclusivity period had expired. Even since that time, the regulatory barriers to generic entry under Hatch-Waxman mean that excluding an approved generic from the market buys additional time during which the patentee has market exclusivity.

Transaction costs change the picture somewhat. If bringing and winning an infringement suit costs $1 million, the patentee might be willing to pay the infringement defendant up to that much to exit the market because the cost of the settlement would be lower than the cost of an injunction. [80]

(A). *Overview of Hatch-Waxman Provisions*

Conceptually, the problem of exclusion payments can arise whenever the patentee has an incentive to postpone determination of the validity of its patent. Practically, the problem of exclusion payments has arisen in antitrust law primarily in the pharmaceutical industry because of its unique patent rules. The 1984 Hatch-Waxman legislation attempted to balance the pioneer drug manufacturers' innovation incentives against the need to facilitate market entry by manufacturers of equivalent generic products. [81] Because these concerns lay jointly in the domains of both the patent law and the law that governs FDA approval of new drug products, the Hatch-Waxman legislation included an extensive series of amendments to both the patent and federal drug statutes. [82]

A major focal point of Hatch-Waxman was the prompt resolution of patent infringement disputes between pioneers and potential generic entrants. [83] Hatch-Waxman introduced three pertinent innovations: (1) a patent "listing" requirement directed to the pioneer, [84] (2) a 30-month stay of the FDA's approval of the generic product whenever a patentee sues an infringer, [85] and (3) a 180-day exclusivity period benefitting the first generic producer to enter the market once a patent expires. [86] Each of these affects the bargaining dynamic in modern pioneer/generic pharmaceutical patent litigation, and each can be criticized as presenting opportunities for either unilateral anticompetitive behavior on the part of the pioneer or pioneer/generic collusion in the form of anticompetitive settlements.

When a pioneer drug manufacturer seeks FDA approval for a new product by filing a New Drug Application (NDA), the pioneer must list any patents having product or method-of-use claims that would be infringed by a generic producer. [87] Listing provides notice to potential generic producers, but it also presents pioneers with an opportunity to force a series of downstream consequences having the potential to hinder competition. Collateral disputes have now arisen over the "listability" of particular patents or types of patent claims. [88] After the Federal Circuit held in *Mylan v. Thompson* that there was no cause of action for delisting an improperly-listed drug on the Orange Book, Congress passed 21 U.S.C. § 355(j)(5)(C)(ii) to create a counterclaim to a patent infringement suit requiring the FDA to correct an improperly listed patent on the Orange Book. [88.1] Such a challenge was at issue in *Caraco Pharmaceutical Laboratories v. Novo Nordisk*. [88.2] The issue in that case was whether a method patent was properly listed on the Orange Book if it covered just one of multiple possible uses for a drug, even though the generic in that case sought to use a different method. The Federal Circuit held that it did, [88.3] but the Supreme Court reversed. The Court held the generic could bring a claim for correction of the Orange Book where the patent was properly listed on the Orange Book but the listing should be narrowed to exclude the generic's noninfringing use. The Court did not directly opine on antitrust matters, but it did characterize the use of overbroad listing codes in the Orange Book as "anticompetitive." [88.4]

One of the key downstream consequences of a patent listing in a pioneer's NDA is the prospect that FDA approval of a competitor's generic product will be stayed for 30 months. [89] A potential entrant into the generic market can secure FDA approval by filing an Abbreviated New Drug Application (ANDA), which asserts that the generic product is a bioequivalent of the pioneer product. [90] Where the pioneer's product or method of use is the subject of patent protection, and the pioneer has listed the patents, the generic's ANDA must also include one of four certifications concerning the impact of the pioneer's listed patents on the generic's proposed manufacturing activity. [91] Of greatest relevance here is the Paragraph IV certification, under which the ANDA applicant asserts that the relevant patent is invalid or not infringed [92] and provides a detailed notice (known as "2(B)(I) notice") to the pioneer, including a detailed opinion supporting the assertions of invalidity or noninfringement. [93]

When the generic makes a Paragraph IV certification, the pioneer has 45 days from the date of the 2(B)(i) notice to sue for infringement. [94] If the pioneer does not timely file such a suit, the ANDA approval "shall be made effective immediately." [95] If the pioneer does timely file, ANDA approval is effective "upon the expiration of the 30-month period" beginning on the date of receipt of the (2)(B)(i) notice, although the court may order a shorter or longer period where "either party to the action failed to reasonably cooperate in expediting the action." [96] If a court concludes in a final decision that the patent is invalid or not infringed prior to the expiration of the 30-month stay, ANDA approval is effective as of the date of that court decision. [97]

The existence of a single 30-month stay materially affects the bargaining calculus between pioneer and generic in a patent infringement suit because it is the equivalent of an automatic preliminary injunction, which courts would be reluctant to issue in a normal patent suit. Further, until 2004 the Hatch-Waxman provisions created the potential for a pioneer to invoke multiple 30-month stays by successively listing new patent information in the Orange Book relevant to a given drug product. [98] The prospect of multiple 30-month stays presented an opportunity for "evergreening," a form of anticompetitive behavior that does not exist in ordinary patent infringement litigation. Regulatory and legislative changes effective in 2004 deal effectively with the problem of multiple 30-month stays, both by giving a generic ANDA applicant sued for patent infringement the right to assert a counterclaim challenging the listing of information in the Orange Book [99] and by limiting patentees to a single 30-month stay for any given drug, regardless of the number of patents listed as covering that drug. [100]

The final Hatch-Waxman innovation of relevance here—the 180-day exclusivity period—also may make pioneer/generic pharmaceutical patent settlements fundamentally different from other patent infringement settlements. [101] Under the Hatch-Waxman legislation, after a first generic producer files an ANDA containing a Paragraph IV certification, subsequent ANDAs filed by other generic producers for the same drug product "shall be made effective not earlier than" 180 days after (1) the date on which the first generic begins marketing the generic product [102] or (2) the date of a court decision holding the patent invalid or not infringed, whichever is earlier. [103] Until 1998, the FDA conditioned the 180-day market exclusivity period on the requirement that the first generic ANDA filer have successfully defended against a patent infringement suit. [104] In *Mova Pharmaceutical Corp. v. Shalala*, the D.C. Circuit struck down this practice. [105] The FDA now grants the exclusivity period to the first generic ANDA filer whether or not the pioneer has sued the generic for patent infringement. [106] Indeed, most grants of 180-day exclusivity today come not from successful challenges to patents but from generic companies that obtain entry rights through settlements, often settlements with cash payments attached. [106.1]

The 180-day exclusivity period offers the potential for collusive settlement arrangements between pioneers and generics. A pioneer could initiate a patent infringement suit against a first generic ANDA filer and settle the litigation with an exclusion payment to the generic, under which the generic would delay commercialization of the generic product, thus postponing the commencement of the 180-day exclusivity period and locking other generics out of the market. [107] Until 2004, such an agreement could keep out other generics indefinitely, because until the first generic actually entered the market no others would have the right to do so. Congress changed the law effective in 2004 to provide that the first generic to file an ANDA is entitled to only 180 days of generic exclusivity and forfeits that exclusivity if it fails to enter the market within a reasonable time. [108] This new provision reduces, but certainly does not eliminate, the gains from anticompetitive settlements. Agreements that exclude generic competitors since that time can still delay generic entry, either directly (if the first ANDA filer agrees to an entry date and therefore can still obtain its generic exclusivity) or because the FDA approval process takes time, so that other generics will not be able to enter as quickly. [108.1]

The Federal Trade Commission now requires disclosure of patent settlements so that it can evaluate them for anticompetitive effects. The government has prosecuted companies that failed to disclose their settlements.

[109] According to an FTC study based on those reported settlements, out of 20 final settlement agreements resolving patent litigation between pioneers and first generic ANDA filers through 2001, 14 contained waiting period provisions—that is, provisions mandating that the generic wait for a specified period of time, ending on or before the date the patent expired, before entering the market. [110] Nine of the agreements studied by the FTC involved payments from the pioneer to the generic. [111] Payments under the nine agreements ranged from $1.75 million to $132.5 million total. [112] An updated study of settlements filed during 2003 and 2004 found 14 agreements settling patent litigation, with none involving an exclusion payment, presumably because of antitrust scrutiny. [113] But by ##### 2005, as courts grew more and more lenient in their antitrust treatment, [114] pharmaceutical companies were once again using exclusion payments. Three of 16 settlements in 2005, 7 of 10 in 2006, and 14 of 33 in 2007 involved such a payment. The numbers continued to increase as antitrust claims against exclusion payments foundered; 19 settlements in 2009, 31 settlements in 2010, and 28 settlements in 2011 included exclusion payments. [114.1]

(B). *Caselaw*

Court and agency decisions evaluating exclusion payments have led to widely different outcomes, ranging from per se illegality to per se legality and including various sorts of rule of reason analysis in between. Some of this variation can be explained by the particular factual circumstances of the various cases, but there is also a split among the circuits about how to treat exclusion payments.

What does seem clear is that exclusion payment settlements must be assessed on the antitrust merits. Some settling parties have argued that their settlement should be immune from antitrust scrutiny because it relates to a lawsuit, which is in turn a government petition. A variant of this argument holds that if the parties ask the judge to approve the settlement, that request cloaks the underlying settlement with immunity.

The problem with this argument is that the anticompetitive consequences of the exclusion payment flow from the agreement between the private parties, not from the result of the petition to the court or from any action by that court. To apply *Noerr* immunity to all settlement agreements would mark a major shift in the scope of antitrust law. As one commentator put it, the consequences would be “staggering…entire industries may be monopolized, prices fixed, and have their markets divided, without anyone being the wiser.” [115] Not surprisingly, courts have generally rejected such claims. [116]

Per se analysis. An exclusion payment is a payment by a company to an actual or potential competitor in exchange for that competitor exiting the market. In the absence of a valid intellectual property right, there seems little question that this sort of market allocation agreement among horizontal competitors would be illegal *per se*. [117] The Sixth Circuit has applied that approach to Hatch-Waxman exclusion payments as well. In *In re Cardizem CD Antitrust Litigation*, [118] the patentee Hoechst and the generic Andrx entered into an agreement during patent litigation under which Hoechst would pay Andrx $10 million a quarter, in return for which Andrx would neither enter the market nor seek to prosecute the suit in which it was a defendant to a conclusion. The effect of the agreement was to delay the onset of the 180-day generic exclusivity period, since the parties agreed to extend rather than terminate the litigation, and therefore to delay indefinitely the entry of other generic competitors, who were required to wait until the expiration of Andrx's 180-day exclusivity. Andrx was ultimately paid nearly $90 million under the agreement. The Sixth Circuit declared the agreement illegal *per se*:

> By delaying Andrx's entry into the market, the Agreement also delayed the entry of other generic competitors, who could not enter until the expiration of Andrx's 180-day period of marketing exclusivity, which Andrx had agreed not to relinquish or transfer. There is simply no escaping the conclusion that the Agreement, all of its other conditions and provisions notwithstanding, was, at its core, a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States, a classic example of a *per se* illegal restraint of trade. [119]

The court properly rejected the defendant's objection that the two parties were not horizontal competitors because over the life of the agreement they did not produce competing drugs. Under that rationale, parties to horizontal market division agreements would almost never be classified as competitors, because the whole purpose of the agreement is to eliminate their competition with one another. [120]

The court also rejected the argument that the agreement was "reasonably ancillary to procompetitive activity" [121] because it simply settled a patent infringement dispute. The court pointed out that the agreement barred the generic manufacturer's entry into the market even after the patent infringement suit was decided, and also barred it from marketing other generic drugs that were at the time not subject to any patent infringement litigation. Further, the effect of the agreement, when combined with the workings of the Hatch-Waxman Act, was to keep out third parties as well by creating a bottleneck behind the first generic filer, which was entitled to 180 days of generic exclusivity before any other generic could enter. [121.1] The court also rejected the argument that because the agreement provided that the generic manufacturer might obtain a license to produce the drug at some future time, it amounted to an ancillary rather than naked restraint.

Subsequent courts have emphasized the particular facts of *Cardizem* in distinguishing its application of the per se rule. In particular, the fact that the agreement did *not* settle the lawsuit, but affirmatively required it to continue, made it clear that the goal of the agreement was not to reduce litigation costs but instead to take advantage of a flaw in the design of the regulatory system. [121.2] Nonetheless, a review of the court's opinion makes it clear that it is the horizontal agreement to eliminate competition, not merely the continuation of the litigation, that drove its conclusion.

Similarly, the Federal Trade Commission imposed a rule of "presumptive" (though not per se) illegality in its decision in *In re Schering Plough Corp.* [122] The FTC had brought a case challenging an agreement by Schering Plough to pay a generic to delay entry into the market. The administrative law judge held that the agreement was not illegal. The FTC unanimously reversed the ALJ's decision in *Schering-Plough.* The Commission found that Schering and its generic competitors violated § 5 of the FTC Act by settling patent litigation over the drug K-Dur 20 in return for an exclusion payment. In this case, unlike in *Cardizem*, the patentee and the generic actually settled the underlying lawsuit. The Commission rejected the idea that settlements were entitled to special treatment: "We recognize that litigation settlements can conserve public and private resources and create other efficiencies. This does not mean, however, that all settlements are procompetitive." [123] The Commission adopted a presumption of illegality, but not quite a per se rule: "Absent proof of other offsetting considerations, it is logical to conclude that the quid pro quo for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise." [124]

While the Commission's approach did not explicitly adopt a rule of per se illegality, in practice it is likely to have that effect. As the Sixth Circuit noted in *Cardizem*, the justifications pharmaceutical companies have so far offered for exclusion payments are unpersuasive:

> [T]he Agreement cannot be fairly characterized as merely an attempt to enforce patent rights or an interim settlement of the patent litigation. As the plaintiffs point out, it is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness in inhibiting competitors by paying the only potential competitor $40 million per year to stay out of the market. Nor does the fact that this is a "novel" area of law preclude *per se* treatment. To the contrary, the Supreme Court has held that "'[w]hatever may be its peculiar problems and characteristics, the Sherman Act, so far as price-fixing agreements are concerned, establishes one uniform rule applicable to all industries alike.'" [125]
>
> Application of a rule of presumptive illegality will likely have the same effect as a per se rule in the case of exclusion payments, simply because there is no plausible procompetitive reason to enter into such an agreement.

Rule of reason analysis; importance of patent validity. Other courts have proven more receptive to the arguments of pharmaceutical companies. Most of the alternatives proposed by those who favor exclusion payments in some circumstances require a more searching inquiry into the merits than does the Sixth Circuit-FTC approach. [126] We discuss those approaches in this section.

Valley Drug Co., Inc. v. Geneva Pharmaceuticals, Inc. [127] refused to apply the per se rule to an exit payment settlement that seemed anticompetitive on its face. Abbott was the pioneer manufacturer of Hytrin, the name brand of a drug whose active ingredient was terazosin. Its basic patent had expired but over the years Abbott had obtained additional patents for other forms of the terazosin compound and methods of preparing it. When generic makers Geneva and Zenith filed ANDAs on generic versions and sought delisting of Abbott's later patents, Abbott filed infringement claims. Zenith and Abbott then entered a settlement agreement under which Zenith promised not to pursue its delisting claim against Abbott and acknowledged the validity of Abbott's subsequent patents. In exchange, Abbott promised to pay Zenith a sum exceeding $25 million per year for staying out of the terazosin market until a different generic manufacturer should enter. Abbott also entered an agreement with Geneva under which Abbott agreed to pay Geneva $4.5 million monthly, and Geneva agreed not to market its generic terazosin pending the outcome of an infringement suit on the principal subsequent Abbott patent. The invalidity of that patent was established in a decision affirmed by the Federal Circuit. [128]

The Eleventh Circuit rejected the district court's decision that these agreements constituted per se antitrust violations. The district court had noted that, like the deal at issue in *Cardizem*, the agreement with Zenith did not even “settle” the patent litigation, but rather prolonged a market allocation while that litigation was pending.

The Eleventh Circuit reasoned from the premise that a valid patent gives its owner a right to exclude to the conclusion that the payment for exclusion was not an unwarranted extension of the patent. “To the extent that Zenith and Geneva agreed not to market admittedly infringing products before the '207 patent expired or was held invalid, the market allocation characterization is inappropriate.” The court noted that “[t]he effect of the Geneva Agreement on the production of Geneva's infringing generic terazosin product may have been no broader than the potential exclusionary effect of the '207 patent.” But that observation does not factor in the considerable ex ante doubt about the validity of the '207 patent. [129] The large size of the exit payment indicates that the value to the patentee of keeping the generic off the market derived not from the patent itself, which would have excluded without the need for compensation, but was in fact an effort to purchase a right of exclusion the law might not provide.

The court also concluded that the fact that the patents were found invalid did not establish per se illegality, because at the time the agreements were formed, invalidity had not been finally established. We have no quarrel with that proposition and agree with the court's conclusion “that exposing settling parties to antitrust liability for the exclusionary effects of a settlement reasonably within the scope of the patent merely because the patent is subsequently declared invalid would undermine the patent incentives.” The right analysis for exclusion settlements is based on the ex ante assessment of the patent's validity, not on how the patent ultimately fares ex post in the courts. Many settlement agreements settle disputes on patents that are subsequently found invalid. The problematic thing about large exit payments to infringement defendants is that they raise a strong inference that the parties believed ex ante the patent is invalid.

Indeed, the court also noted that the existence of the '207 patent “may” have entitled Abbott to a preliminary injunction pending the appeal, which would also have had the effect of keeping the rivals out of the market. But the important point seems to be that rather than obtaining a preliminary injunction, Abbott chose to pay very large sums of money in order to obtain its rivals' agreement not to enter its markets. A firm willing to pay roughly $75 million per year in order to keep an alleged infringer out of the market when a successful preliminary injunction would have done the same thing is indicating that the prospects for a preliminary injunction were poor.

Speaking of the size of the exit payments the court observed:

> It may be that the size of the payment to refrain from competing, sometimes called a “reverse payment” or an “exit payment,” raises the suspicion that the parties lacked faith in the validity of the patent, particularly

> when those payments are non-refundable in the event that the patentee prevails on the infringement claim (as a bond posted as part of a preliminary injunction would be). However, in the instant case and given the state of the current record, it is difficult to infer from the size of the payments alone that the infringement suits lacked merit. We do not know, for example, what lost profits Abbott expected from generic competition or what profits Geneva and Zenith expected to gain from entry, the risk of the defendants' inability to satisfy a judgment, or the litigation costs each side expected to save from settlement. We do not know how much of the payment might have been in exchange for provisions of the Agreements other than Zenith's and Geneva's acknowledgment of validity. Without these facts we cannot confidently draw the conclusion, merely from the size of the payments, that there were no genuine disputes over the validity of the patent. [130]

Finally, the court noted that the agreement in question also included a clause prohibiting the entrants from marketing “any” generic terazosin product. While the reference is unclear, an agreement requiring a rival not to produce a product that is not covered by the patent is unlawful per se.

The Eleventh Circuit did not conclude that the agreement in question was necessarily legal, however. Instead, the court concluded that the legality of the settlement agreement depended on whether the patentee would in fact have won the underlying patent suit. If the patentee would have won, the settlement did not exclude generic competition that should have been permitted. If the patentee would have lost, by contrast, a settlement that excludes the generic reduces competition and is therefore illegal.

Valley Labs seems to doom the courts to relitigating the settled patent case, with the additional handicap that the parties with the best knowledge and incentive to dispute the validity and scope of the patent are now aligned on the same side. Indeed, that is exactly what happened on remand. The district court conducted a detailed analysis of the likely outcome of the patent litigation and found that the patent owner's arguments were “weak and unlikely to result in a District Court finding that the '207 patent was valid.” [131] As a result, the district court concluded that the patent could not shield the patentee's exclusion payment from antitrust liability, and went on to find that since the patent would have been held invalid, the settlement agreement including the payment was per se unlawful. Other courts applying a similar analysis have refused to dismiss antitrust complaints that depended in part on claims that the exclusion payments limited competition outside the lawful scope of the patent. [131.1]

We think the Eleventh Circuit gave too much weight to the grant of a patent. The law does presume issued patents are valid. But it also permits and indeed encourages competitors to challenge doubtful patents, and when patents are challenged in court nearly half are held invalid. To presume the validity of a patent even when, as in *Valley Labs*, the circumstances of the exclusion payment cast doubt on its strength is to give the patentee a more powerful right than the patent laws intended. While the ultimate result in the district court was the same, it would seem more reasonable to infer likely invalidity from the size of the exclusion payment rather than put district courts to the detailed reconstruction of hypothetical litigation outcomes the district court conducted.

While the size of the exclusion payment is surely relevant in deciding whether the parties thought ex ante the patent was valid or not, exactly how that information should be used is open to question. The district court in *Ciprofloxacin Hydrochloride* correctly pointed out that courts are ill-equipped to engage in post-hoc reconstruction of how patent validity litigation would have been resolved. [132] But if a court is not to engage in an analysis of patent validity, and instead is to choose between an assumption that the patent is valid and an assumption that it is invalid, the question then becomes how the fact that the patentee paid the defendant a substantial sum—$398 million in *Cipro*—to settle the case rather than have a court decide validity should incline the court to choose between those assumptions.

The *Cipro* district court reasoned that since the amount Bayer paid was only 26.5 percent of the profit it expected to make through the expiration of the patent, it followed that Bayer thought the odds of losing were only 26.5 percent. We think the general thrust of the inquiry is correct: the more a patentee is willing to pay, the less good its patent is likely to be. A simple equation of percentage of expected profits may not accurately predict the

parties' beliefs about the validity of the patent, however. First, while $398 million is a small share of Bayer's expected profits, the court did not consider what share it represents of the generic manufacturer's expected profits—but presumably it is a much higher number. [133] The parties would be willing to settle for any number in a range that makes both of them better off; what number they pick in that range depends on the information they have and their bargaining skills. Thus, we might be able to conclude that Bayer thought there was *at least* a 26.5 percent chance of losing the patent, but we don't know how high it thought the odds were, because we don't know how much more than that it would have been willing to pay. And we know that the generic could have though the chance of validity was as high as 100% and still agreed to the deal. Second, Bayer expected $1.5 billion in profits *over the life of the patent.* If other generic entrants could eventually challenge the patent, as the district court found likely, what Bayer paid for was not complete insulation from invalidity but a delay of several years in any ultimate finding of invalidity. While the district court found the possibility of other entrants challenging the patent to weigh against a finding of antitrust liability, we think it properly has the opposite effect: Bayer was willing to pay at least $398 million to secure, not $1.5 billion in profits, but whatever profits it would make in the period before the next challenge to the patent could be heard, presumably a significantly smaller number. Thus, Bayer's estimate of the risk of invalidity as measured by the size of its payment is correspondingly higher.

In short, the size of the exclusion payment is relevant evidence that a court applying a rule of reason inquiry should consider. But courts need to exercise care in drawing accurate inferences from the size of the payment.

The Eleventh Circuit moved even further away from a rule of per se illegality in reversing the FTC's decision in *Schering Plough Corp. v. FTC*. [134] There, the court concluded that "neither the rule of reason nor the per se analysis is appropriate in this context." [135] Instead, the court constructed a three-part test in which it looked at "(1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects." [136] Stated that way, the Eleventh Circuit's legal test does not seem dissimilar to the FTC's rule of reason approach. But the court diverged sharply from the FTC—and from its own prior decision in *Valley Labs* —in engaging in an all-but-conclusive presumption that an issued patent was valid. Because it presumed that a patent that had not yet been invalidated was necessarily valid, at least unless the patentee's infringement lawsuits were shams, [137] the court found no expansion beyond the proper legal scope of the patent. [137.1] The court was also quite critical of the FTC's fact-finding in the case before it.

With respect, we think the Eleventh Circuit again gave too much deference to the Patent and Trademark Office. The PTO engages in a cursory look at the hundreds of thousands of applications it receives every year, and grants patents to the overwhelming majority of such applications. When patents are enforced, their validity is almost always at issue, and 46 percent of the patents litigated to judgment are determined to be invalid. While patents enjoy a strong legal presumption of validity, it is not an irrebuttable one. Antitrust plaintiffs should be entitled to adduce evidence tending to suggest that the patent would likely have been held invalid. A large payment from the patentee to the accused infringer is strong evidence of probable invalidity, for the reasons we have already explained. It is also evidence that consumers are, on expectation, losing competition they might otherwise have enjoyed.

Schering Plough's all-but-conclusive presumption did serve the interests of judicial economy, since it prevented the courts from having to inquire carefully into who would likely have won the suit had it been litigated to judgment, as the district court had to do in *Valley Labs*. But it achieved that result at the cost of ignoring the competitive realities of the case. Consider, for instance, that the accused infringers in the underlying litigation not only challenged the validity of the patent but also argued that they did not infringe. While the patent statute places the burden of proving invalidity on the accused infringer, the burden of proving infringement is on the patent owner. By the same reasoning the Eleventh Circuit used, courts should conclusively presume patents valid whenever a settlement occurs, but must for the same reason conclusively presume that those patents were not infringed. [138] And if they are (presumptively) not infringed, any settlement that excludes the generic

necessarily "exceeds the scope" of "the exclusionary potential of the patent." [139] That would be an irrational result, but so is conclusively presuming that a patent is valid. In both cases, the error lies in substituting a conclusive presumption for the actual evidence before the court.

Whether the FTC was right to conclude that the payment at issue in *Schering* was sufficient evidence of invalidity is another matter. The *Schering* case is complicated by the fact that the patentee's payment not only settled a validity dispute but also purchased another drug from the payee. To be evidence of invalidity in this context, a payment must clearly exceed the fair market value of the drug being purchased. The evidence before the ALJ on this point was disputed. [140] But the complexity here arguably results from the deliberate effort of the settling parties to obfuscate the nature of the settlement by bundling together transactions that could easily be separated. Given the increasing tendency of settling parties to complicate their settlements to dissuade antitrust scrutiny, courts might reasonably place the burden on the settling parties to demonstrate how value should be allocated among the various portions of the transaction in cases like *Schering*. [141]

Extreme deference; per se legality. The Second Circuit has shown even more lenient treatment toward exclusion payments than the Eleventh Circuit. In *In re Tamoxifen Citrate Antitrust Litig.*, [142] the patentee Zeneca had sued Barr for infringement of its breast cancer drug, but the district court held the patent invalid. While the case was pending on appeal, the parties settled, with the patentee agreeing to pay Barr and its supplier $65 million and also give it a license to produce an authorized generic version of the drug, but only if the parties could collectively persuade the court to vacate the judgment of invalidity, which it ultimately did. The plaintiffs also alleged that Barr agreed to, and did, use its 180-day generic exclusivity to keep other ANDA filers from entering the market. Those subsequent ANDA filers, unable to rely on the vacated judgment of invalidity, ultimately lost their validity challenges against Zeneca's patent.

Notwithstanding these facts, the district court granted Zeneca's Rule 12(b)(6) motion to dismiss a variety of antitrust challenges to the settlement, and the Second Circuit affirmed. The court began by invoking "our longstanding adherence to the principle" that "courts are bound to encourage" the settlement of litigation. [143] It then refused to inquire into the validity of the patent, reasoning that

> We cannot judge this post-trial, pre-appeal settlement on the basis of the likelihood *vel non* of Zeneca's success had it not settled but rather pursued its appeal. As the Supreme Court noted in another context, "[i]t is just not possible for a litigant to prove in advance that the judicial system will lead to any particular result in his case." *Whitmore v. Arkansas*, 495 U.S. 149, 159 - 60, 110 S. Ct. 1717, 109 L.Ed.2d 135 (1990). Similarly, "[n]o one can be *certain* that he will prevail in a patent suit." *Asahi Glass,* 289 F. Supp. 2d at 993 (emphasis in original). [144]

The court accordingly viewed itself as put to a choice of treating the agreement as either per se legal or per se illegal. But rather than draw from the factual circumstances (the prior court holding of invalidity, the substantial payment to Barr, which plaintiffs alleged "greatly exceeded" anything Barr could have made by winning the patent suit, [145] Zeneca's allowing Barr to enter the market in competition with it, Barr's use of its 180-day exclusivity to delay entry by other generics) the conclusion that the parties believed at the time of the settlement that the patent would likely have been held invalid, the court drew the opposite presumption: "so long as the patent litigation is neither a sham nor otherwise baseless, the patent holder is seeking to arrive at a settlement in order to protect that to which it is presumably entitled: a lawful monopoly over the manufacture and distribution of the patented product." [146] The result is that in the Second Circuit, exclusion payments are legal per se unless the underlying lawsuit is not only weak but a sham, a standard that is virtually impossible to surmount. [147]

The court believed that adopting this rule of per se legality was the only way to encourage settlements, "even if it leads in some cases to the survival of monopolies created by what would otherwise be fatally weak patents." [148]

But there are plenty of ways to settle a pharmaceutical patent case without paying your competitor to stay out of the market, [149] and during the early part of the 21st Century dozens of pharmaceutical patent owners settled

their disputes without an exclusion payment. The court also believed that "[i]t is too late in the journey for us to alter course," [150] a curious statement given that it was the first appellate court to apply a rule of per se legality or to hold that it could be applied on a motion to dismiss.

Judge Pooler dissented from almost every conclusion of the panel majority:

> I differ with both the majority's standard for pleading a Hatch-Waxman-settlement antitrust violation and with several subsidiary holdings, conclusions, or assumptions. The requirement that—unless an antitrust plaintiff demonstrates that a settlement agreement exceeds the scope of the patent—it must show that the settled litigation was a sham, i.e., objectively baseless, before the settlement can be considered an antitrust violation is not soundly grounded in Supreme Court precedent and is insufficiently protective of the consumer interests safeguarded by the Hatch-Waxman Act and the antitrust laws. Beyond that overarching difference, the majority has, in my view, wrongly (1) accorded dispositive deference to Zeneca's patent rights when its patent had been declared invalid at the time of the settlement; (2) focused on subsequent litigation concerning patent validity rather than the litigation posture at the time of settlement; (3) held that the district court could not assess the likelihood that Zeneca would succeed on appeal; (4) held that plaintiffs insufficiently alleged a conspiracy between Barr and Zeneca to deploy Barr's paragraph IV certification when it would delay the market entry of another generic manufacturer; and (5) failed to recognize that whether plaintiffs' injuries stem from the alleged Barr/Zeneca conspiracy or from the failure of other generics to invalidate the patent cannot be resolved on the pleadings. [151]

We think Judge Pooler has the better of the argument, on several grounds. First, the case arose on a motion to dismiss, and it seems unreasonable to hold that there is no set of facts in which an exclusion payment greater than the value of the entire litigation could be anticompetitive. Second, the merits do matter, as Judge Pooler explained:

> A Hatch-Waxman settlement, by definition, protects the parties' interests as they see them. Whether it also promotes the public's interest depends on the facts. If the validity of the patent is clear, and the generic company receives a license to market the patent holder's product, competition is increased. However, if, as in this case, the patent has already been shown to be vulnerable to attack and the generic manufacturer is paid to keep its generic product off the market, it is hard to see how the public benefits. [152]

Finally, as in *Cardizem* the result of this settlement was allegedly not merely to clear the way for subsequent patent challengers, but rather to use the Hatch-Waxman process to prevent any such challenges. That allegation resonates with the behavior of other pharmaceutical patent owners in other cases, and in any event surely seemed to allege a conspiracy to restrict competition.

The Federal Circuit followed the Second Circuit's approach of extraordinary deference in *In re Ciprofloxacin Hydrochloride Antitrust Litigation,* [153] affirming a grant of summary judgment for the defendant in a case in which the patentee paid $398 million to exclude the generic competitor. The Federal Circuit announced that it was applying a rule of reason analysis. [154] It found "no evidence that the Agreements created a bottleneck on challenges to the '444 patent or otherwise restrained competition outside the 'exclusionary zone' of the patent." [155] So far, that analysis seems consistent with the Eleventh Circuit approach in *Valley Labs*. But the Federal Circuit departed from the rule of reason approach by limiting the inquiry into the merits of the underlying patent suit to the very limited question of "whether there was evidence of sham litigation or fraud before the PTO." [156] "In the absence of evidence of fraud before the PTO or sham litigation, the court need not consider the validity of the patent in the antitrust analysis of a settlement agreement involving a reverse payment." [157] The court reasoned that the patent was presumed valid and conferred the right to exclude others. It leapt from those facts to the statement that "[a] settlement is not unlawful if it serves to protect that to which the patent holder is legally entitled—a monopoly over the manufacture and distribution of the patented invention." [158] In making this leap,

the Federal Circuit ignored the evidence suggesting that the parties might have believed the patent invalid at the time of the settlement, including a payment to the generic that was so large that the generic would make more money by settling than by invalidating the patent. The Federal Circuit's unwillingness to consider evidence bearing on validity led it to adopt what is in effect a rule of per se legality, at least absent the rare case of sham litigation. As the Third Circuit put it in *K-Dur*:

> As a practical matter, the scope of the patent test does not subject reverse payment agreements to any antitrust scrutiny. As the antitrust defendants concede, no court applying the scope of the patent test has ever permitted a reverse payment antitrust case to go to trial. [158.1]

Quick Look. In *In re K-Dur Antitrust Litigation*, [158.2] the Third Circuit canvassed all of the approaches described above, and rejected the Second/Federal Circuit approach as overly deferential. The Third Circuit criticized the *Tamoxifen* approach as creating an "almost unrebuttable presumption of patent validity," one that "assumes away the question being litigated in the underlying patent suit, enforcing a presumption that the patent owner would have prevailed." [158.3] The court pointed out that the presumption of validity is a procedural mechanism for allocating a burden of proof, not a substantive legal requirement. [158.4] And it observed that generics, not patent owners, prevail in most pharmaceutical patent disputes. Notably, in *K-Dur*, the settled dispute concerned infringement, not validity, and the court observed that even if the presumption of validity were substantive it should not apply to infringement disputes.

The Third Circuit held that Supreme Court precedent counseled against complete deference to the PTO's decision to grant the patent. The Court has repeatedly emphasized the importance of allowing challenges to potentially invalid patents, and in *Edward Katzinger Co. v. Chicago Metallic Manufacturing Co.*, [158.5] the Court identified "the broad public interest in freeing our competitive economy from the trade restraints which might be imposed by price-fixing agreements stemming from narrow or invalid patents." [158.6] Exclusion payments based on invalid patents, the Third Circuit held, presented the same risk as price fixing of sharing monopoly based on an invalid patent. The court acknowledged the general policy favoring settlement, but held that it "should not displace countervailing public policy objectives." [158.7] It also noted strong evidence that parties could still settle pharmaceutical disputes without exclusion payments.

Ultimately, the Third Circuit stopped short of a per se illegality standard, adopting instead a "quick look rule of reason analysis based on the economic realities of the reverse payment settlement." [158.8] The court weighted the outcome of that quick look quite strongly toward a finding of illegality, however:

> [T]he finder of fact must treat any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market as *prima facie* evidence of an unreasonable restraint of trade, which could be rebutted by showing that the payment (1) was for a purpose other than delayed entry or (2) offers some pro-competitive benefit.
>
> …
>
> We agree, moreover, with the FTC that there is no need to consider the merits of the underlying patent suit because "[a]bsent proof of other offsetting consideration, it is logical to conclude that the *quid pro quo* for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise." *In re Schering–Plough Corp.,* Final Order, 136 F.T.C. at 988. Of course, a patent holder may attempt to rebut plaintiff's *prima facie* case of an unreasonable restraint of trade by arguing that there is in fact no reverse payment because any money that changed hands was for something other than a delay in market entry. Alternatively, the patent holder may attempt to rebut the *prima facie* case by demonstrating that the reverse payment offers a competitive benefit that could not have been achieved in the absence of a reverse payment. This second possible defense attempts to account for the—probably rare—situations where a reverse payment increases competition. For example, a modest cash payment that enables a cash-starved generic manufacturer to avoid

bankruptcy and begin marketing a generic drug might have an overall effect of increasing the amount of competition in the market. [158.9]

Trends. The overall effect of *Tamoxifen* and *Cipro* remains to be seen, but it has clearly exacerbated an existing split in the circuits, one the Supreme Court has repeatedly refused to confront or resolve. Decisions in the Eleventh Circuit [158.10] and the California Court of Appeal [158.11] have gravitated toward the extraordinarily deferential Second Circuit standard. The Eleventh Circuit decision in *Watson* is notable because it departs significantly from the Eleventh Circuit's prior position in *Valley Drug*, adopting instead the Second Circuit formulation that as long as a lawsuit is not a sham it is categorically immune from antitrust scrutiny. While the court attempts to characterize its decision as consistent with *Valley Drug*, the decision is fundamentally different. *Valley Drug* held that the antitrust case depended on whether the underlying patent suit had merit; *Watson* rejects that as a consideration altogether. *Valley Drug* said the size of an exclusion payment could be relevant evidence, though it was not determinative there; *Watson* held the opposite. While the resulting law in the Eleventh Circuit is uncertain, *Watson* does represent a trend in the courts away from any serious antitrust scrutiny of exclusion payments despite their competitive consequences. [158.12]

As a result of cases showing extreme deference to settlements that involve exclusion payments, pharmaceutical litigants, who had shifted to settling disputes without exclusion payments in the early years of the 21st century, have shifted back to paying to exclude competitors. Still the FTC remains active in this area, and filed a complaint against a reverse payment by Cephalon in 2008. [159] And private actions against reverse payments continue, including an award of damages against Mylan Pharmaceuticals for its reverse payments in 1997 and 1998. [160]

Nonetheless, there are reasons to believe the cases giving extreme deference to settlements do not represent a consensus. In *Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, [160.1] an appeal from the district court in *Cipro*, a Second Circuit panel suggested dissatisfaction with the *Tamoxifen* rule. While the court was bound by *Tamoxifen*, and accordingly affirmed the grant of summary judgment to defendants, it noted "several reasons why this case might be appropriate for reexamination by our full Court." [160.2] The court noted that the government and members of Congress had repudiated *Tamoxifen*, that exclusion payments were on the rise as a result of the opinion, and that *Tamoxifen* erred in its characterization of the effects of Hatch-Waxman. Nonetheless, the full court refused to revisit *Tamoxifen*, with Judge Pooler again dissenting. [160.3] And the Third Circuit approach in *In re K-Dur* represents a significant step away from the Second Circuit standard. As we discuss below, we believe the Third Circuit approach is the right one.

(C) *Solutions to the Problem of Pharmaceutical Settlements*

In the paragraphs that follow, we suggest how we believe antitrust should treat exclusion payments.

Exclusion payments were not common in patent infringement litigation prior to the passage of the Hatch-Waxman amendments. [161] Undoubtedly, what has increased their attraction under that statute is the fact—unique to pharmaceutical patents—that a properly defined settlement-plus-exclusion-payment not only keeps the immediate infringement defendant out of the market for a time but also keeps other generic firms from entering as well. [162] In *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, [163] the court reasoned that if a patent was likely invalid, paying off a challenger was unlikely to be a successful strategy because other challengers would line up to attack the patent, and the patentee couldn't afford to pay them all. This logic makes sense outside the pharmaceutical context, but it doesn't work under Hatch-Waxman. The regulatory scheme for pharmaceutical patents means that by settling with an ANDA filer, a patent owner can delay entry by any other generic for three years or more. This delay in the possible invalidation of the patent is likely to be valuable to pharmaceutical patent owners. [164]

In the typical Hatch-Waxman case involving a large exclusion payment, the rule of reason as traditionally conceived under antitrust law will not be a fruitful avenue of inquiry. The very fact that the pioneer finds it worthwhile to pay a large exclusion payment tends to establish market power. [165] It also suggests some inherent uncertainty as to the validity or scope of the patent; as noted above, a patentee that is certain of winning will not pay anything more than its anticipated remaining legal fees in exchange for an agreement by a generic to exit the market. [166] The very fact of that uncertainty suggests that exclusion payments are anticompetitive—that on average such agreements exclude at least some generics that in fact had a legal right to compete.

In a law review article, Tom Cotter acknowledges the antitrust risks to exclusion payments. [167] He argues, however, that it will often be rational for pharmaceutical patentees to agree to make exclusion payments to generic competitors, and therefore that the mere existence and size of those payments should not automatically incline courts to find that they are illegal. [168] We do not think it follows that because it is rational for the patentee to agree to an exclusion payment, that payment cannot be anticompetitive. Far from it. Breaking down the equations in Cotter's model [169] makes it clear that there are two components of any rational exclusion payment. The first is the cost of continued litigation. Even a patentee sure to win would be willing to pay a defendant a sum up to the cost of the lawsuit to end the litigation and avoid that cost. The second, more significant number is the value of eliminating competition that the patentee could not expect ex ante to exclude after trial. A close look at Cotter's model confirms that the size of the expected exclusion payments is inversely related to the strength of the patentee's case: The less likely the patentee is to win, the more it is willing to pay a generic to stay out of the market. [170] Thus, if the patentee is sure to win, the second number is zero and the exclusion payment is no more than the cost of litigation. [171] But if the patentee has a 25 percent chance of losing, it is willing to pay up to 25 percent of the value of its monopoly to exclude its competitors without a trial. [172] The reason the patentee is willing to make this payment is precisely because the settlement will permit it to exclude competition from the market, whereas if it went to trial there is a 25 percent chance that the patent would be held invalid or not infringed and the market would become competitive. Far from justifying exclusion payments on competitive grounds, therefore, Cotter's model demonstrates that those payments are inherently anticompetitive. On expectation, the patentee is paying for an advantage that it could not get if it went to trial. [173] And because patent owners make much more during the period of exclusivity than generics can expect to make in competition, a payment that seems small to a patentee may in fact be as much or more than the generic can expect to make it if wins. Thus, the patentee sacrifices a small amount of its profits by sharing it with the generic, and the generic in turn is better off being paid to stay out of the market than it would be if it won the suit and entered. But consumers suffer, because they don't get the benefits of competition and lower prices for drugs covered by invalid patents.

We suggest the following rule. In an antitrust challenge, a payment from a patentee to an infringement defendant for the latter's exit from the market is presumptively unlawful, shifting the burden of proof to the infringement plaintiff. The infringement plaintiff can defend by showing both (1) that the ex ante likelihood of prevailing in its infringement lawsuit is significant, and (2) that the size of the payment is no more than the expected value of litigation and collateral costs attending the lawsuit. [174] The rationale for limiting exclusion payments to litigation costs is noted above. In addition, we think it important that the court make at least some limited inquiry into the merits of a settlement that requires the defendant to exit the market. If exclusion payments are illegal, the parties will have an incentive to conceal those payments, perhaps by turning them into noncash compensation (the patentee's forbearance from price competition in a separate market, for example). If the patent lawsuit is a sham, and the accused infringer still agrees to leave the market without a substantial exclusion payment, it is worth making sure there isn't another payment hidden in the transaction. This oversight necessarily requires some inquiry into the merits of the IP suit, but we think it need not be particularly searching. The goal is merely to ensure that there is a legitimate dispute being settled. [174.1]

In assessing such payments, it is important to keep in mind that the *ex ante* effect of a harsh rule will not necessarily impede settlement; it may simply make the settlement take on a different form. For example, suppose the law absolutely forbade a patentee from paying an infringement defendant for its agreement not to practice technology covered by the patent. The result may make a settlement more difficult to achieve, but it could just as easily change the course of the settlement—for example, to one in which the infringement defendant obtains a license from the patentee. Since such a settlement permits more competition while allowing the parties to avoid the costs of uncertainty, it is preferable to a settlement based on exclusion payments. [175]

Tom Cotter derides this as akin to a compulsory licensing rule, [176] but in fact antitrust law is not compelling licensing of any sort. The patentee need not license at all. For the cost of a lawsuit, the patentee can simply enforce its rights without any fear of antitrust liability. If the patent is valid and infringed, the elimination of competition that results is entirely justified by IP policy. It is only where the patentee wants to eliminate competition through collusion that antitrust law properly takes notice.

Nor is there any significant risk that a rule limiting exclusion payments would reduce the legitimate value of pharmaceutical patent rights. As Carl Shapiro has pointed out, a patent is not a right to exclude but rather a right to try to exclude. [177] Indeed, a significant number of patents that make it to court are ultimately held invalid or not infringed. [178] The legitimate exclusion value of a pharmaceutical patent is the power it actually confers over competition, which is in turn a function of the scope of the patent and its chance of being held valid. What the pharmaceutical patentees who agree to exclusion payments seek is something more: a guaranteed insulation from competition, without the risk that the patent is held invalid. IP policy does not offer such a guarantee and does not immunize from antitrust scrutiny those who seek it by entering into agreements that exclude potential competitors. [178.1]

(D) *Agreements to Delay Entry*

Another alternative to exclusion payments is for the parties to settle a patent dispute by delaying entry by the generic. A stipulated injunction that lasts for less than the term of the patent is more likely to reflect the uncertain outcomes of patent litigation. For example, if a patent with ten years of term remaining is 50 percent likely to be held invalid, the parties might settle the case by agreeing that the generic will not enter for a specified number of years but then will be able to enter without paying a royalty. [179] The parties have effectively split the uncertainty costs of the litigation. [180] More important, assuming delayed entry is not coupled with an exclusion payment, it does not align the incentives of pioneer and generic litigants: Generics will want the delay to be as short as possible, and patentees to make the delay as long as possible. This means that we can expect that an agreement to delay entry reflects the parties' joint assessment of the likely outcome of the litigation. A delayed entry agreement therefore allows the parties to capture the economic significance of uncertainty as to patent outcome. [181]

As a result, we think courts ordinarily should not object to a delayed-entry settlement not induced by an exclusion payment, because it is likely to be an estimate of the expected outcome by the parties with the best information about that outcome. [182] Several caveats are necessary, however. First, delayed entry is an efficient solution only if it is not coupled with any form of exclusion payment. If a pioneer pays a generic to delay entry, the likelihood is that the delay does *not* in fact represent the expected outcome of litigation but rather has been biased toward later entry by the payment. Second, if the delayed-entry settlement has the effect of bottling up other entrants, for example by allowing the generic to “park” its 180-day exclusivity, it may distort competition even without an exclusion payment. [182.1] Finally, there is always a risk that the parties will successfully conceal an exclusion payment, for example by agreeing under the table that the parties will cartelize the industry after entry. To prevent this risk, courts should engage in at least some scrutiny of delayed entry settlements to ensure that the IP right is not a mere sham employed to conceal what is essentially a cartel. [183] This oversight

necessarily requires some inquiry into the merits of the IP suit, but we think it need not be particularly searching. The goal is merely to ensure that there is a legitimate dispute being settled.

(E) *Exclusion Payments in Settlements of Patent Interference Proceedings*

In the earlier parts of this section, we analyzed exclusion payments in the context of settlements of patent infringement proceedings, especially proceedings involving owners of patented, brand name pharmaceuticals suing producers of generic substitutes. In this section, we change the context to patent interference proceedings.

A patent interference is an administrative proceeding [184] whose main focus is to resolve the issue of priority of invention—that is, determining which party, among competing claimants for the same patent rights, was the "first to invent" the contested subject matter, as defined under United States patent law.

Interferences ordinarily involve very difficult questions of proof, and many of the quite detailed regulations that govern the conduct of interference proceedings deal with the order of proof and the nature of evidence that may be submitted to establish invention. [185] Proof of a complete act of invention under United States patent law requires proof of both conception (defined as the "formation in the mind of the inventor of a definite and permanent idea of the complete and operative invention") and reduction to practice (defined as (1) the construction of a physical embodiment of the invention and a showing that the embodiment works for its intended purposes; or (2) the filing of a patent application that discloses a claimed invention in compliance with 35 U.S.C. § 112, ¶1). [186] Under specified circumstances, proof of priority of invention also requires evidence of the inventor's diligence in reducing an invention to practice. [187] Abandonment, suppression, or concealment of an invention once made may also be relevant in determining priority. [188]

Conception, reduction to practice, diligence and abandonment are not ironclad concepts. They are highly fact-intensive. Indeed, the interference procedures rely on the application filing date, rather than the true date of invention, as a more practical and reliable starting point for determining priority of invention. The first applicant to file an application covering the contested subject matter is deemed the "senior party" for purposes of the interference proceeding and enjoys a presumption of being the first to invent. "Junior" parties must overcome the presumption, often by presenting evidence of an earlier conception and reduction to practice. Interference proceedings might take on the characteristics of a tennis match in which the parties take turns presenting successively earlier invention evidence or contesting the opponent's offering of early invention evidence.

Interference proceedings can be complex and time-consuming, frequently consuming months or even years. In these respects, interference proceedings are not unlike patent infringement litigation. As with patent infringement litigation, the parties may routinely consider the prospect of settling the proceeding short of final judgment. For example, the parties may enter into an agreement in which one party concedes priority of invention and abandons any claim of exclusive rights to the contested subject matter, thus clearing the way for the PTO to issue patent protection over the contested subject matter to the other party, assuming that all other requisites of patentability are satisfied.

In deciding whether to settle ordinary patent infringement litigation, the parties may consider the risk of having patent rights invalidated and the risk of exposure to liability for damages accruing from past infringement (though such damages will be absent from some cases, notably cases in which a defendant generic producer seeks to begin competing with a plaintiff's patented brand name product), in addition to the likely costs of the litigation. In deciding whether to settle patent interference proceedings, the calculation may be different. No patent infringement damages are at stake in an interference, which distinguishes interferences from some (though certainly not all) patent infringement cases. Moreover, where the interference involves competing applicants, neither party stands to lose *existing* patent rights; instead, the interference loser stands to lose potential patent rights over the contested subject matter, the value of which may be difficult to pin down, at least as compared to existing patent rights.

The settlement of interference proceedings may present opportunities for collusion. For example, suppose that A, the first filer (senior party), is in an interference with B, the second filer (junior party). If A prevails and the PTO issues a patent to A on the contested subject matter, the patent will run for 20 years measured from A's filing date. If B prevails and the PTO issues a patent to B, the patent will run from 20 years measured from B's filing date, a later date than A's filing date. If A and B mutually agree that the patent rights would be more valuable if shifted later in time, they may decide that it would be mutually advantageous to settle the interference by an agreement in which A concedes that B was the first to invent, thus clearing the way for issuance of a patent to B, with a payment or favorable licensing terms to A. This was the effect of the settlement in *Medimmune, Inc. v. Genentech, Inc.* [189] The parties to a priority dispute before the district court agreed to settle the dispute by awarding priority not to the existing patentee, Celltech, but to the junior party, Genentech. Because of the patent term rules then in force and the fact that the interference proceeding ultimately took over a decade to resolve, the result was that Genentech was ultimately awarded a patent that expired years after Celltech's patent would have.

Other opportunities for collusion also exist. In the course of the interference, the junior party may uncover prior art or other evidence that raises questions about the validity or enforceability of any patent rights that issue (to either party) from the interference. The parties in that circumstance may decide that giving one party a patent is preferable to neither one getting a patent, and settle the interference accordingly.

The patent statute recognizes the potential for collusive settlements of interferences, requiring the settling parties to file copies of interference settlement agreements with the PTO, where the agreements can be made available to antitrust enforcement authorities. [190] In *United States v. Singer Mfg. Co.*, [191] the Court held that the parties had violated section 1 of the Sherman Act by colluding to divide markets and exclude foreign competitors, in part by settling interference disputes in a way that preserved patent rights over sewing machine technologies. The majority did not expressly hold the interference settlements illegal, but Justice White's concurrence would have found that settling an interference "at least in part[] to prevent an open fight over validity" was itself a violation of the antitrust laws. [192] In *Medimmune,* by contrast, the Federal Circuit held that "[t]he settlement of disputes such as priority in patent interferences is not a presumptive violation of antitrust law; such violation requires a showing of market power and other antitrust predicates." [193] The court reasoned that:

> The antitrust posture that MedImmune urges for patent interferences can discourage if not prevent settlements, placing unnecessary burdens on the courts and the PTO. Priority determinations may raise complex questions of law and scientific fact, and the delays in their resolution by the PTO are notorious; settlement can, as here, expedite resolution of difficult issues. The *per se* or presumptive illegality urged by MedImmune for interference settlements is contrary to both precedent and policy… [194]

Curiously, having held that interference settlements were subject to the rule of reason, the court did not resolve the legality of the settlement before it under the rule of reason, instead seeming to conclude that rejecting per se illegality was dispositive.

We suggest that the three-part framework that we presented for settlements generally in Chapter 7 be applied to evaluate interference settlement agreements. In addition, where the interference settlement involves an exclusion payment to the interference loser as discussed in the preceding sections, we suggest that courts and antitrust authorities find that the exclusion payment is presumptively unlawful if the exclusion payment exceeds the expected value of the interference (e.g., the royalties that the interference loser would have collected from the winner had the loser prevailed) plus costs of the interference. This presumption is weaker than the presumption articulated in the preceding sections, reflecting the fact that in an interference settlement each side has a chance at patent exclusivity, and the party giving up that chance must be compensated. Our proposed rule deliberately leaves more room for exclusion payments in the settlement of interference proceedings.

(F) *Standing to Sue*

Agreements delaying generic entry into branded pharmaceutical markets injure two significant groups. First are second and subsequent entrants into the generic market, who under the Hatch-Waxman Act are precluded from entering until 180 days after the first generic producer receives market rights for its product and starts producing. Second are consumers, who are denied the benefit of the considerable reduction in prices that commonly attends the entry of generics into competition with a branded drug.

Establishing antitrust standing to sue can be difficult for second and subsequent producers of generics, particularly if they cannot show a sufficient degree of "preparedness" to enter the market. [196] In *Andrx*, antitrust counterclaimant Biovail's application to be a second entrant into the market for a generic drug was delayed by an agreement between the first generic applicant, Andrx, and the owner of the patent on the principal pharmaceutical. The agreement effectively delayed FDA approval and Biovail's ability to enter the market. [197]

Assuming that the agreement between Andrx and the patentee was unlawful, the district court held that Biovail's complaint failed to show standing to sue because it did not allege that it reasonably anticipated (1) that the FDA would have approved its generic drug application when given the opportunity, and (2) failed to allege that once approval was given it actually would have entered with the generic substitute. As a result, Biovail "fail[ed] to plead sufficient intent and preparedness to enter the market," which is a requirement for plaintiff standing. [198]

Although the D.C. Circuit agreed with the district court that the pleading was insufficient, it disagreed with the lower court's dismissal with prejudice. Rather, Biovail should be able to plead and show the requisite elements. [199]

The D.C. Circuit also disagreed with Andrx's argument that Biovail could not establish causation because its exclusion from the market was caused by the FDA's failure to approve its generic, not by the agreement between Andrx and the patentee:

> By accepting payments from HMRI [the patentee], Andrx received the benefit of the 180-day exclusivity period without starting the clock [on the period before a second generic maker could enter]. By agreeing with HMRI to share HMRI's profits from the sale of Cardizem CD, it was able to exclude other competitors from entering the market. Andrx's commitment not to trigger the running of the 180-day exclusivity period could have caused Biovail's injury (assuming FDA approval was probable and it was sufficiently prepared to enter the market) by denying it the ability to proceed to market with its own generic version. Although the 180-day provision of the Hatch-Waxman Amendments legally barred it from selling its product, Andrx's manipulation of the exclusivity period trigger date extended the legal bar. [200]

The court also rejected Andrx's argument that Biovail could not prove injury because its application would have been delayed 2005, as courts grew more and more lenient in their antitrust treatment, [114] pharmaceutical companies were once again using exclusion payments. Three of 16 settlements in 2005, 7 of 10 in 2006, and 14 of 33 in 2007 involved such a payment. The numbers continued to increase as antitrust claims against exclusion payments foundered; 19 settlements in 2009, 31 settlements in 2010, 28 settlements in 2011, and 40 settlements in 2012 included exclusion payments. [114.1]

(B) *Caselaw before* Actavis

To begin, it seems clear that exclusion payment settlements must be assessed on the antitrust merits. Some settling parties have argued that their settlement should be immune from antitrust scrutiny because it relates to a lawsuit, which is in turn a government petition. A variant of this argument holds that if the parties ask the judge to approve the settlement, that request cloaks the underlying settlement with immunity.

The problem with this argument is that the anticompetitive consequences of the exclusion payment flow from the agreement between the private parties, not from the result of the petition to the court or from any action by that court. To apply *Noerr* immunity to all settlement agreements would mark a major shift in the scope of antitrust law. As one commentator put it, the consequences would be “staggering…entire industries may be monopolized,

prices fixed, and have their markets divided, without anyone being the wiser." [115] Not surprisingly, courts have generally rejected such claims. [116] And the Supreme Court in *Actavis* clearly saw no reason to give settlements special immunity from antitrust scrutiny.

Court and agency decisions evaluating exclusion payments during the 2000s led to widely different outcomes, ranging from per se illegality to per se legality and including various sorts of rule of reason analysis in between. Some of this variation can be explained by the particular factual circumstances of the various cases, but there was also a split among the circuits about how to treat exclusion payments.

Per se analysis. The Sixth Circuit found Hatch-Waxman exclusion payments illegal per se. In *In re Cardizem CD Antitrust Litigation*, [117] the patentee Hoechst and the generic Andrx entered into an agreement during patent litigation under which Hoechst would pay Andrx $10 million a quarter, in return for which Andrx would neither enter the market nor seek to prosecute the suit in which it was a defendant to a conclusion. The effect of the agreement was to delay the onset of the 180-day generic exclusivity period, since the parties agreed to extend rather than terminate the litigation, and therefore to delay indefinitely the entry of other generic competitors, who were required to wait until the expiration of Andrx's 180-day exclusivity. Andrx was ultimately paid nearly $90 million under the agreement. The Sixth Circuit declared the agreement illegal *per se*. Similarly, the Federal Trade Commission imposed a rule of "presumptive" (though not per se) illegality in its decision in *In re Schering Plough Corp.* [118]

Subsequent courts emphasized the particular facts of *Cardizem* in distinguishing its application of the per se rule. In particular, the fact that the agreement did *not* settle the lawsuit, but affirmatively required it to continue, made it clear that the goal of the agreement was not to reduce litigation costs but instead to take advantage of a flaw in the design of the regulatory system. [119]

Rule of reason analysis; importance of patent validity. Other courts proved more receptive to the arguments of pharmaceutical companies. *Valley Drug Co., Inc. v. Geneva Pharmaceuticals, Inc.* [120] refused to apply the per se rule to an exit payment settlement that seemed anticompetitive on its face. Abbott was the pioneer manufacturer of Hytrin, the name brand of a drug whose active ingredient was terazosin. Its basic patent had expired but over the years Abbott had obtained additional patents for other forms of the terazosin compound and methods of preparing it. When generic makers Geneva and Zenith filed ANDAs on generic versions and sought delisting of Abbott's later patents, Abbott filed infringement claims. Zenith and Abbott then entered a settlement agreement under which Zenith promised not to pursue its delisting claim against Abbott and acknowledged the validity of Abbott's subsequent patents. In exchange, Abbott promised to pay Zenith a sum exceeding $25 million per year for staying out of the terazosin market until a different generic manufacturer should enter. Abbott also entered an agreement with Geneva under which Abbott agreed to pay Geneva $4.5 million monthly, and Geneva agreed not to market its generic terazosin pending the outcome of an infringement suit on the principal subsequent Abbott patent. The invalidity of that patent was established in a decision affirmed by the Federal Circuit. [121]

The Eleventh Circuit reasoned from the premise that a valid patent gives its owner a right to exclude to the conclusion that the payment for exclusion was not an unwarranted extension of the patent.

The Eleventh Circuit did not conclude that the agreement in question was necessarily legal, however. Instead, the court concluded that the legality of the settlement agreement depended on whether the patentee would in fact have won the underlying patent suit. If the patentee would have won, the settlement did not exclude generic competition that should have been permitted. If the patentee would have lost, by contrast, a settlement that excludes the generic reduces competition and is therefore illegal.

The Eleventh Circuit moved even further away from a rule of per se illegality in reversing the FTC's decision in *Schering Plough Corp. v. FTC*. [122] There, the court concluded that "neither the rule of reason nor the per se analysis is appropriate in this context." [123] Instead, the court constructed a three-part test in which it looked at

"(1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects." [124] Stated that way, the Eleventh Circuit's legal test does not seem dissimilar to the FTC's rule of reason approach. But the court diverged sharply from the FTC—and from its own prior decision in *Valley Labs*—in engaging in an all-but-conclusive presumption that an issued patent was valid. Because it presumed that a patent that had not yet been invalidated was necessarily valid, at least unless the patentee's infringement lawsuits were shams, [125] the court found no expansion beyond the proper legal scope of the patent. [126]

Extreme deference; per se legality. The Second and Federal Circuits showed even more lenient treatment toward exclusion payments than the Eleventh Circuit. In *In re Tamoxifen Citrate Antitrust Litig.*, [127] the patentee Zeneca had sued Barr for infringement of its breast cancer drug, but the district court held the patent invalid. While the case was pending on appeal, the parties settled, with the patentee agreeing to pay Barr and its supplier $65 million and also give it a license to produce an authorized generic version of the drug, but only if the parties could collectively persuade the court to vacate the judgment of invalidity, which it ultimately did. The plaintiffs also alleged that Barr agreed to, and did, use its 180-day generic exclusivity to keep other ANDA filers from entering the market. Those subsequent ANDA filers, unable to rely on the vacated judgment of invalidity, ultimately lost their validity challenges against Zeneca's patent.

Notwithstanding these facts, the district court granted Zeneca's Rule 12(b)(6) motion to dismiss a variety of antitrust challenges to the settlement, and the Second Circuit affirmed. The court created a virtually irrebuttable presumption: "so long as the patent litigation is neither a sham nor otherwise baseless, the patent holder is seeking to arrive at a settlement in order to protect that to which it is presumably entitled: a lawful monopoly over the manufacture and distribution of the patented product." [128] The result is that in the Second Circuit, exclusion payments are legal per se unless the underlying lawsuit was not only weak but a sham, a standard that is virtually impossible to surmount. [129]

The Federal Circuit followed the Second Circuit's approach of extraordinary deference in *In re Ciprofloxacin Hydrochloride Antitrust Litigation,* [130] affirming a grant of summary judgment for the defendant in a case in which the patentee paid $398 million to exclude the generic competitor. The Federal Circuit announced that it was applying a rule of reason analysis. [131] It found "no evidence that the Agreements created a bottleneck on challenges to the '444 patent or otherwise restrained competition outside the 'exclusionary zone' of the patent." [132] So far, that analysis seems consistent with the Eleventh Circuit approach in *Valley Labs*. But the Federal Circuit departed from the rule of reason approach by limiting the inquiry into the merits of the underlying patent suit to the very limited question of "whether there was evidence of sham litigation or fraud before the PTO." [133]

These courts put a very strong premium on the policy of encouraging settlement, something echoed by Chief Justice Roberts' dissent in *Actavis*. They worried that pharmaceutical companies would not be able to settle patent litigation without a reverse payment.

Quick Look. In *In re K-Dur Antitrust Litigation*, [134] the Third Circuit canvassed all of the approaches described above, and rejected the Second/Federal Circuit approach as overly deferential.

Ultimately, the Third Circuit stopped short of a per se illegality standard, adopting instead a "quick look rule of reason analysis based on the economic realities of the reverse payment settlement." [135] The court weighted the outcome of that quick look quite strongly toward a finding of illegality, however:

> [T]he finder of fact must treat any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market as *prima facie* evidence of an unreasonable restraint of trade, which could be rebutted by showing that the payment (1) was for a purpose other than delayed entry or (2) offers some pro-competitive benefit.
>
> …

> We agree, moreover, with the FTC that there is no need to consider the merits of the underlying patent suit because "[a]bsent proof of other offsetting consideration, it is logical to conclude that the *quid pro quo* for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise." [136]

(C) Actavis

Federal Trade Commission v. Actavis, Inc., [137] involved a fairly typical reverse-payment scenario. Solvay Pharmaceuticals obtained a patent on AndroGel. Actavis and Paddock Laboratories both filed ANDA applications alleging that the patent was invalid. Solvay sued and obtained an automatic 30-month stay of Actavis's ANDA approval. The FDA approved Actavis's ANDA after the stay expired while the case was pending, but the parties settled, with Actavis agreeing to delay entry for nine years in exchange for payments ranging from $19-30 million each year; the other generics were also paid smaller amounts to drop their challenges. The generics also promised to help Solvay promote its brand-name drug, and the settling parties claimed that this marketing assistance was the reason for the payments, but the Federal Trade Commission alleged that those services had "little value" and that the "true point of the payments was to compensate the generics for agreeing not to compete." [138]

The district court granted defendants' motion to dismiss the FTC's antitrust complaint, and the Eleventh Circuit affirmed, holding that "absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent." [139]

The Supreme Court reversed, 5-3. In an opinion by Justice Breyer, the Court held that "reverse payment settlements . . . can sometimes violate the antitrust laws." [140] In so doing, the Court flatly rejected the "scope of the patent" test endorsed by the Second, Eleventh, and Federal Circuits:

> Solvay's patent, if valid and infringed, might have permitted it to charge drug prices sufficient to recoup the reverse settlement payments it agreed to make to its potential generic competitors. And we are willing to take this fact as evidence that the agreement's "anticompetitive effects fall within the scope of the exclusionary potential of the patent." 677 F.3d, at 1312. But we do not agree that that fact, or characterization, can immunize the agreement from antitrust attack. [141]

The Court emphasized that this "scope of the patent" test would apply only to patents known to be valid and infringed. But that was the very question the settlement avoided resolving:

> The patent here may or may not be valid, and may or may not be infringed. . . . But an *invalidated* patent carries with it no such right. And even a valid patent confers no right to exclude products or processes that do not actually infringe. [142]

Importantly, the Court made it clear that the relevant question was not merely what rights patent law would have conferred. "[I]t would be incongruous to determine antitrust legality by measuring the settlement's anticompetitive effects solely against patent policy, rather than by measuring them against precompetitive antitrust policies as well." [143] Rather, both antitrust and patent policies were relevant to determining the proper "scope of the patent monopoly – and consequently antitrust immunity – that is conferred by a patent. . . . Whether a particular restraint lies beyond the limits of the patent monopoly is a *conclusion* that flows from [traditional antitrust] analysis and not . . . its starting point." [144] The Court cited a number of its precedents applying antitrust scrutiny to patent-related settlements, observing that those cases "seek to accommodate patent and antitrust policies, finding challenged terms and conditions unlawful unless patent law policy offsets the antitrust law policy strongly favoring competition." [145]

The Court acknowledged the argument made by Chief Justice Roberts' dissent (and the Eleventh Circuit) that the "strong interest in settlement" justified deference to reverse-payment settlements. But it found that argument insufficient to drive the result, for several reasons. First, the Court emphasized the settlement's "potential for genuine adverse effects on competition." [146] As the Court explained,

> The payment in effect amounts to a purchase by the patentee of the exclusive right to sell its product, a right it already claims but would lose if the patent litigation were to continue and the patent were held invalid or not infringed by the generic product. . . .
>
> But settlement on the terms said by the FTC to be at issue here—payment in return for staying out of the market—simply keeps prices at patentee-set levels, potentially producing the full patent-related [] monopoly return while dividing that return between the challenged patentee and the patent challenger. The patentee and the challenger gain; the consumer loses. Indeed, there are indications that patentees sometimes pay a generic challenger a sum even larger than what the generic would gain in profits if it won the paragraph IV litigation and entered the market. [147]

And while in other markets such a sizeable payment might signal weakness and invite entry by other competitors, the nature of the Hatch-Waxman Act makes that unlikely, both because the settling first generic retains 180 days of generic exclusivity and because the subsequent entrant will be subject to an automatic 30-month stay. [148]

The Court acknowledged that there might be legitimate justifications for a reverse payment; we discuss this in more detail in section D, below. But that wasn't a reason to create an exception from the normal rules of antitrust law; defendants will be free to offer those justifications in the course of an antitrust case. [149] Notably, the Court expressed skepticism of many of those reasons:

> Although the parties may have reasons to prefer settlements that include reverse payments, the relevant antitrust question is: What are those reasons? If the basic reason is a desire to maintain and to share patent-generated monopoly profits, then, in the absence of some other justification, the antitrust laws are likely to forbid the arrangement. [150]

To apply the scope of the patent test to bar any challenge "throws the baby out with the bath water, and there is no need to take that drastic step." [151] That is particularly true because the Court's rule "does not prevent litigating parties from settling their lawsuit. They may, as in other industries, settle in other ways, for example by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point." [152]

Despite concluding that reverse payments will often be anticompetitive, the Court rejected the quick look approach adopted by the Third Circuit and proposed by the Federal Trade Commission in favor of a rule of reason analysis. In so doing, however, the Court was careful to note that this rule of reason analysis need not be as full-blown as a normal antitrust case. Rather, the Court left to the lower courts the task of

> structur[ing] antitrust litigation so as to avoid, on the one hand, the use of antitrust theories too abbreviated to permit proper analysis, and, on the other, consideration of every possible fact or theory irrespective of the minimal light it may shed on the basic question— that of the presence of significant unjustified anticompetitive consequences. [153]

We turn in the next section to how courts might accomplish that task.

(D) *Applying the Rule of Reason to the Problem of Pharmaceutical Settlements*

The question then becomes how to apply the rule of reason inquiry envisioned by the Supreme Court in *Actavis.* In the paragraphs that follow, we suggest how we believe antitrust should treat exclusion payments in light of the *Actavis* decision and the economics of pharmaceutical patent litigation.

In the typical Hatch-Waxman case involving a large exclusion payment, the rule of reason as traditionally conceived under antitrust law will not be a fruitful avenue of inquiry. The very fact that the pioneer finds it worthwhile to pay a large exclusion payment tends to establish market power. [154] It also suggests some inherent uncertainty as to the validity or scope of the patent; a patentee that is certain of winning will not pay anything more than its anticipated remaining legal fees in exchange for an agreement by a generic to exit the market. [155] The very fact of that uncertainty suggests that exclusion payments are anticompetitive—that on average such agreements exclude at least some generics that in fact had a legal right to compete. The reason the patentee is willing to make a payment that exceeds its litigation costs is precisely because the settlement will permit it to exclude competition from the market, whereas if it went to trial there is a chance that the patent would be held invalid or not infringed and the market would become competitive. On expectation, the patentee is paying for an advantage that it could not get if it went to trial. [156]

The *Actavis* opinion contains a number of strong hints that the Court understands this and does not intend the rule of reason to be unbounded or to allow settling parties to justify their conduct on the ground that the patentee acquired certainty. Indeed, Tom Cotter suggests that "[i]n reality, the Court appears to have all but in name adopted the presumptive illegality approach it purported to reject." [157]

First, the Court found the amount of the payment quite significant. Large payments, it suggested, could themselves be "strong evidence" of an antitrust violation:

> The rationale behind a payment of this size cannot in every case be supported by traditional settlement considerations. The payment may instead provide strong evidence that the patentee seeks to induce the generic challenger to abandon its claim with a share of its monopoly profits that would otherwise be lost in the competitive market. [158]

Indeed, the Court seemed to think that evidence of a sufficiently large payment was itself enough to prove the anticompetitive nature of a settlement:

> An unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival. And that fact, in turn, suggests that the payment's objective is to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market—the very anticompetitive consequence that underlies the claim of antitrust unlawfulness. The owner of a particularly valuable patent might contend, of course, that even a small risk of invalidity justifies a large payment. But, be that as it may, the payment (if otherwise unexplained) likely seeks to prevent the risk of competition. And, as we have said, that consequence constitutes the relevant anticompetitive harm. In a word, the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness . . . [159]

For this reason, the Court concluded that "it is normally not necessary to litigate patent validity to answer the antitrust question." [160] The size of the payment stands in for what would otherwise be an unworkable reexamination of the underlying patent merits. It "provide[s] a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself." [161]

Second, when the Court considered (at two different points in the opinion) what sorts of justifications the settling parties might offer for a reverse payment, it pointed to only two: the size of the payment and whether the payment was for something other than delayed entry. [162] Notably, in both cases, the Court's discussion of the size of the reverse payment focused on "its scale in relation to the payor's anticipated future litigation costs," [163] not to risk aversion or the patentee's desire to convert an uncertain patent right into a certain one without

litigation. [164] While the Court was careful to note that "[t]here may be other justifications," [165] it did not see the elimination of the risk of invalidity as one of those justifications. To the contrary, the Court emphasized the importance to the public of weeding out bad patents. It rejected the dissent's call for immunity from antitrust scrutiny, saying that "[i]t would be difficult to reconcile the proposed right with the patent-related policy of eliminating unwarranted patent grants so the public will not "continually be required to pay tribute to would-be monopolists without need or justification." [166]

The Court's repeated references to the size of the payment in relation to litigation costs as the critical consideration, coupled with multiple comments indicating that the validity of the patent would not ordinarily be at issue and statements in Part III that a rule of reason analysis need not consider every argument, led us to believe that a rule of reason analysis under *Actavis* will be simpler and more structured than a normal antitrust rule of reason case. The plaintiff may not need to show market power; the Court seemed to think market power could be presumed from the nature of the settlement and the regulatory framework. Nor would a court have to look very far for anticompetitive effect; the reverse payment by its nature had such an effect, the Court suggested. [167] So the focus of a rule of reason case after *Actavis* is likely to be on justifications for the settlement. Courts should look for some reason to think that a reverse payment had something other than its ordinary effect of persuading the generic to delay entry or stay off the market altogether. A payment to avoid expected future litigation costs might suffice or a payment that was for something other than delay, such as a co-branding deal.

A harder question is whether the settling parties should be entitled to introduce evidence that the patent was in fact valid. It seems clear that proof of invalidity or noninfringement is no longer required to make out an antitrust violation. But what if the patent was later held valid in subsequent patent litigation against other parties? It might seem logical that a later determination of validity (or invalidity) would determine whether the settlement was anticompetitive. In fact, however, decisions prior to *Actavis* have made clear that the right time for assessing the competitive effects of the settlement is at the time of settlement, not afterwards. In *Valley Drug*, for example, the court concluded that the fact that the patents were later found invalid did not establish per se illegality, because at the time the agreements were formed, invalidity had not been finally established. We have no quarrel with that proposition and agree with the court's conclusion "that exposing settling parties to antitrust liability for the exclusionary effects of a settlement reasonably within the scope of the patent merely because the patent is subsequently declared invalid would undermine the patent incentives." [168] The right analysis for exclusion settlements is based on the ex ante assessment of the patent's validity, not on how the patent ultimately fares ex post in the courts. Many settlement agreements settle disputes on patents that are subsequently found invalid. The problematic thing about large exit payments to infringement defendants is that they raise a strong inference that the parties believed ex ante that the patent is invalid. Thus, we are skeptical that subsequent evidence of validity or invalidity ought to carry much weight in the rule of reason inquiry. Certainly the *Actavis* Court did not think it necessary to inquire into validity.

Courts also will have to consider how large a payment will suffice to demonstrate the anticompetitive nature of a reverse payment settlement. We believe that the settling parties can defend by showing that the size of the payment is no more than the expected value of litigation and collateral costs attending the lawsuit. [169] The Court's references to the size of the payment were not measured relative to the patentee's expected profits, but rather to litigation expenses. Thus, the Court thought that a settlement might be legitimate if it "amount[ed] to no more than a rough approximation of the litigation expenses saved through the settlement." [170] A payment in excess of that amount is a payment for something. And if it is not to save litigation costs or to buy some other legitimate service from the generic, it must be to delay generic entry relative to what the parties expected would have happened had the case gone to trial.

The definition of litigation costs will also matter in practice. We think they should be limited to a good faith estimate of the out-of-pocket costs and attorneys' fees that the patentee could expect to pay between the time of the settlement and the time the case was concluded. Although Robert Willig and John Bigelow have suggested

that the value of uncertainty could be included in "litigation costs," [171] we think this impermissibly brings in the value of certain exclusion based on a doubtful patent under the rubric of litigation expenses. The *Actavis* Court viewed buying certainty as an anticompetitive aspect of reverse payment settlements, not as a justification; it would surely not accept elimination of that uncertainty as a "litigation cost." [172]

Finally, we think it important that the court make at least some limited inquiry into the merits of a settlement that requires the defendant to exit the market. If exclusion payments are illegal, the parties will have an incentive to conceal those payments, perhaps by turning them into noncash compensation (the patentee's forbearance from price competition in a separate market, for example). If the patent lawsuit is a sham, and the accused infringer still agrees to leave the market without a substantial exclusion payment, it is worth making sure that there isn't another payment hidden in the transaction. This oversight necessarily requires some inquiry into the merits of the IP suit, but we think it need not be particularly searching. The goal is merely to ensure that there is a legitimate dispute being settled. [173]

Actavis itself is an example of such a case. The settling parties alleged that the payment was for ancillary marketing services provided by the generic; the FTC disputed that and claimed that those services were not worth the money paid. The *Schering Plough* case was similarly complicated by the fact that the patentee's payment not only settled a validity dispute but also purchased another drug from the payee. To be evidence of invalidity in this context, a payment must exceed the fair market value of the drug being purchased. The evidence before the ALJ in *Schering Plough* was disputed. [174] But the complexity here arguably results from the deliberate effort of the settling parties to obfuscate the nature of the settlement by bundling together transactions that could easily be separated. Given the increasing tendency of settling parties to complicate their settlements to dissuade antitrust scrutiny, courts might reasonably place the burden on the settling parties to demonstrate how value should be allocated among the various portions of the transaction in cases like *Schering*. [175]

The legitimate exclusion value of a pharmaceutical patent is the power it actually confers over competition, which is in turn a function of the scope of the patent and its chance of being held valid. What the pharmaceutical patentees who agree to exclusion payments seek is something more: a guaranteed insulation from competition, without the risk that the patent is held invalid. IP policy does not offer such a guarantee and does not immunize from antitrust scrutiny those who seek it by entering into agreements that exclude potential competitors. [176]

(E) *Agreements to Delay Entry*

Another alternative to exclusion payments is for the parties to settle a patent dispute by delaying entry by the generic. A stipulated injunction that lasts for less than the term of the patent is more likely to reflect the uncertain outcomes of patent litigation. For example, if a patent with ten years of term remaining is 50 percent likely to be held invalid, the parties might settle the case by agreeing that the generic will not enter for a specified number of years but then will be able to enter without paying a royalty. [177] The parties have effectively split the uncertainty costs of the litigation. [178] More important, assuming delayed entry is not coupled with an exclusion payment, it does not align the incentives of pioneer and generic litigants: Generics will want the delay to be as short as possible, and patentees to make the delay as long as possible. This means that we can expect that an agreement to delay entry reflects the parties' joint assessment of the likely outcome of the litigation. A delayed entry agreement therefore allows the parties to capture the economic significance of uncertainty as to patent outcome. [179]

As a result, we think courts ordinarily should not object to a delayed-entry settlement not induced by an exclusion payment, because it is likely to be an estimate of the expected outcome by the parties with the best information about that outcome. [180] Indeed, the Supreme Court endorsed such settlements in dictum in *Actavis,* offering them as an alternative to the reverse-payment settlements it found problematic. [181] Several caveats are necessary, however. First, delayed entry is an efficient solution only if it is not coupled with any form of exclusion

payment. If a pioneer pays a generic to delay entry, the likelihood is that the delay does *not* in fact represent the expected outcome of litigation but rather has been biased toward later entry by the payment. Second, if the delayed-entry settlement has the effect of bottling up other entrants, for example by allowing the generic to "park" its 180-day exclusivity, it may distort competition even without an exclusion payment. [182]

Finally, there is always a risk that the parties will successfully conceal an exclusion payment, for example by agreeing under the table that the parties will cartelize the industry after entry. For example, in *In re Skelaxin (Metaxalone) Antitrust Litigation,* the defendants claimed that there was no exclusion payment associated with the settlement. The court refused to dismiss the antitrust case, however, finding evidence that suggested a secret payment in association with the settlement, including secret meetings and alleged statements that the patentee intended to compensate generic companies with whom it was then in litigation. [182.1] To prevent this risk, courts should engage in at least some scrutiny of delayed entry settlements that do not have an apparent payment to ensure that the IP right is not a mere sham employed to conceal what is essentially a cartel. [183]

(F) *Exclusion Payments in Settlements of Patent Interference Proceedings*

In the earlier parts of this section, we analyzed exclusion payments in the context of settlements of patent infringement proceedings, especially proceedings involving owners of patented, brand name pharmaceuticals suing producers of generic substitutes. In this section, we change the context to patent interference proceedings.

A patent interference is an administrative proceeding [184] whose main focus is to resolve the issue of priority of invention—that is, determining which party, among competing claimants for the same patent rights, was the "first to invent" the contested subject matter, as defined under United States patent law.

Interferences ordinarily involve very difficult questions of proof, and many of the quite detailed regulations that govern the conduct of interference proceedings deal with the order of proof and the nature of evidence that may be submitted to establish invention. [185] Proof of a complete act of invention under United States patent law requires proof of both conception (defined as the "formation in the mind of the inventor of a definite and permanent idea of the complete and operative invention") and reduction to practice (defined as (1) the construction of a physical embodiment of the invention and a showing that the embodiment works for its intended purposes; or (2) the filing of a patent application that discloses a claimed invention in compliance with 35 U.S.C. § 112, ¶1). [186] Under specified circumstances, proof of priority of invention also requires evidence of the inventor's diligence in reducing an invention to practice. [187] Abandonment, suppression, or concealment of an invention once made may also be relevant in determining priority. [188]

Conception, reduction to practice, diligence and abandonment are not ironclad concepts. They are highly fact-intensive. Indeed, the interference procedures rely on the application filing date, rather than the true date of invention, as a more practical and reliable starting point for determining priority of invention. The first applicant to file an application covering the contested subject matter is deemed the "senior party" for purposes of the interference proceeding and enjoys a presumption of being the first to invent. "Junior" parties must overcome the presumption, often by presenting evidence of an earlier conception and reduction to practice. Interference proceedings might take on the characteristics of a tennis match in which the parties take turns presenting successively earlier invention evidence or contesting the opponent's offering of early invention evidence.

Interference proceedings can be complex and time-consuming, frequently consuming months or even years. In these respects, interference proceedings are not unlike patent infringement litigation. As with patent infringement litigation, the parties may routinely consider the prospect of settling the proceeding short of final judgment. For example, the parties may enter into an agreement in which one party concedes priority of invention and abandons any claim of exclusive rights to the contested subject matter, thus clearing the way for the PTO to issue patent protection over the contested subject matter to the other party, assuming that all other requisites of patentability are satisfied.

In deciding whether to settle ordinary patent infringement litigation, the parties may consider the risk of having patent rights invalidated and the risk of exposure to liability for damages accruing from past infringement (though such damages will be absent from some cases, notably cases in which a defendant generic producer seeks to begin competing with a plaintiff's patented brand name product), in addition to the likely costs of the litigation. In deciding whether to settle patent interference proceedings, the calculation may be different. No patent infringement damages are at stake in an interference, which distinguishes interferences from some (though certainly not all) patent infringement cases. Moreover, where the interference involves competing applicants, neither party stands to lose *existing* patent rights; instead, the interference loser stands to lose potential patent rights over the contested subject matter, the value of which may be difficult to pin down, at least as compared to existing patent rights.

The settlement of interference proceedings may present opportunities for collusion. For example, suppose that A, the first filer (senior party), is in an interference with B, the second filer (junior party). If A prevails and the PTO issues a patent to A on the contested subject matter, the patent will run for 20 years measured from A's filing date. If B prevails and the PTO issues a patent to B, the patent will run from 20 years measured from B's filing date, a later date than A's filing date. If A and B mutually agree that the patent rights would be more valuable if shifted later in time, they may decide that it would be mutually advantageous to settle the interference by an agreement in which A concedes that B was the first to invent, thus clearing the way for issuance of a patent to B, with a payment or favorable licensing terms to A. This was the effect of the settlement in *Medimmune, Inc. v. Genentech, Inc.* [189] The parties to a priority dispute before the district court agreed to settle the dispute by awarding priority not to the existing patentee, Celltech, but to the junior party, Genentech. Because of the patent term rules then in force and the fact that the interference proceeding ultimately took over a decade to resolve, the result was that Genentech was ultimately awarded a patent that expired years after Celltech's patent would have.

Other opportunities for collusion also exist. In the course of the interference, the junior party may uncover prior art or other evidence that raises questions about the validity or enforceability of any patent rights that issue (to either party) from the interference. The parties in that circumstance may decide that giving one party a patent is preferable to neither one getting a patent, and settle the interference accordingly.

The patent statute recognizes the potential for collusive settlements of interferences, requiring the settling parties to file copies of interference settlement agreements with the PTO, where the agreements can be made available to antitrust enforcement authorities. [190] In *United States v. Singer Mfg. Co.*, [191] the Court held that the parties had violated section 1 of the Sherman Act by colluding to divide markets and exclude foreign competitors, in part by settling interference disputes in a way that preserved patent rights over sewing machine technologies. The majority did not expressly hold the interference settlements illegal, but Justice White's concurrence would have found that settling an interference "at least in part[] to prevent an open fight over validity" was itself a violation of the antitrust laws. [192] In *Medimmune,* by contrast, the Federal Circuit held that "[t]he settlement of disputes such as priority in patent interferences is not a presumptive violation of antitrust law; such violation requires a showing of market power and other antitrust predicates." [193] The court reasoned that:

> The antitrust posture that MedImmune urges for patent interferences can discourage if not prevent settlements, placing unnecessary burdens on the courts and the PTO. Priority determinations may raise complex questions of law and scientific fact, and the delays in their resolution by the PTO are notorious; settlement can, as here, expedite resolution of difficult issues. The *per se* or presumptive illegality urged by MedImmune for interference settlements is contrary to both precedent and policy… [194]

Curiously, having held that interference settlements were subject to the rule of reason, the court did not resolve the legality of the settlement before it under the rule of reason, instead seeming to conclude that rejecting per se illegality was dispositive.

We suggest that the three-part framework that we presented for settlements generally in Chapter 7 be applied to evaluate interference settlement agreements. In addition, where the interference settlement involves an exclusion payment to the interference loser as discussed in the preceding sections, we suggest that courts and antitrust authorities find that the exclusion payment is presumptively unlawful if the exclusion payment exceeds the expected value of the interference (e.g., the royalties that the interference loser would have collected from the winner had the loser prevailed) plus costs of the interference. This presumption is weaker than the presumption articulated in the preceding sections, reflecting the fact that in an interference settlement each side has a chance at patent exclusivity, and the party giving up that chance must be compensated. Our proposed rule deliberately leaves more room for exclusion payments in the settlement of interference proceedings.

(G) *Standing to Sue*

Agreements delaying generic entry into branded pharmaceutical markets injure two significant groups. First are second and subsequent entrants into the generic market, who under the Hatch-Waxman Act are precluded from entering until 180 days after the first generic producer receives market rights for its product and starts producing. Second are consumers, who are denied the benefit of the considerable reduction in prices that commonly attends the entry of generics into competition with a branded drug.

Establishing antitrust standing to sue can be difficult for second and subsequent producers of generics, particularly if they cannot show a sufficient degree of "preparedness" to enter the market. [196] In *Andrx*, antitrust counterclaimant Biovail's application to be a second entrant into the market for a generic drug was delayed by an agreement between the first generic applicant, Andrx, and the owner of the patent on the principal pharmaceutical. The agreement effectively delayed FDA approval and Biovail's ability to enter the market. [197] Assuming that the agreement between Andrx and the patentee was unlawful, the district court held that Biovail's complaint failed to show standing to sue because it did not allege that it reasonably anticipated (1) that the FDA would have approved its generic drug application when given the opportunity, and (2) failed to allege that once approval was given it actually would have entered with the generic substitute. As a result, Biovail "fail[ed] to plead sufficient intent and preparedness to enter the market," which is a requirement for plaintiff standing. [198] Although the D.C. Circuit agreed with the district court that the pleading was insufficient, it disagreed with the lower court's dismissal with prejudice. Rather, Biovail should be able to plead and show the requisite elements. [199]

The D.C. Circuit also disagreed with Andrx's argument that Biovail could not establish causation because its exclusion from the market was caused by the FDA's failure to approve its generic, not by the agreement between Andrx and the patentee:

> By accepting payments from HMRI [the patentee], Andrx received the benefit of the 180-day exclusivity period without starting the clock [on the period before a second generic maker could enter]. By agreeing with HMRI to share HMRI's profits from the sale of Cardizem CD, it was able to exclude other competitors from entering the market. Andrx's commitment not to trigger the running of the 180-day exclusivity period could have caused Biovail's injury (assuming FDA approval was probable and it was sufficiently prepared to enter the market) by denying it the ability to proceed to market with its own generic version. Although the 180-day provision of the Hatch-Waxman Amendments legally barred it from selling its product, Andrx's manipulation of the exclusivity period trigger date extended the legal bar. [200]

The court also rejected Andrx's argument that Biovail could not prove injury because its application would have been delayed in any event if Andrx had decided unilaterally not to market its generic, thus delaying the approval date for the entrant of a second generic manufacturer. The court noted that, whether or not the conduct would have been lawful if undertaken unilaterally, in this case it was allegedly undertaken pursuant to an anticompetitive agreement between Andrx and the patentee.

We think the D.C. Circuit is correct to conclude that a second generic entrant that could have entered earlier but for the settlement has been injured in an antitrust sense by the settlement. In addition, direct purchasers unquestionably have standing to challenge settlements that delay entry. [201]

15.3a2. Authorized Generics; Other Agreements

15.3a2(A) *Authorized Generics*

Not all settlements between pharmaceutical patent owners and generics involve exclusion payments or market division arrangements. We suggested earlier that patent owners could settle suits by permitting the generic challenger to enter the market in exchange for the payment of a license fee, just as patentees in other industries license companies to enter the market in exchange for payment. We believe those licenses do less harm to competition than do exclusion payments, because they permit generic competition in the marketplace, albeit not the unfettered competition that would exist if the patent was invalidated. [201.1]

These so-called “authorized generics” may themselves raise antitrust issues. The introduction of an authorized generic might be viewed as an unlawful exclusionary practice, because it might reduce or even eliminate the incentive of a true generic to enter the market. Generic firms rely on the 180-day exclusivity offered as an incentive to bring lawsuits challenging patents. Arguably, the development of authorized generics is intended by pharmaceutical patent owners as a form of predation, making patent challenges by generics uneconomic by squeezing out the profits associated with a successful patent challenge. The Federal Trade Commission has investigated the issue in detail. [202]

An authorized generic takes one of two forms: a “generic” version of a branded drug either authorized and sold by the branded drug manufacturer itself or granted to a generic manufacturer in exchange for a license fee.

Where the patentee itself sells it own generic version of the branded drug it sells, few antitrust issues arise. The patent owner, acting unilaterally, is presumptively permitted to brand its drug in any way it likes, and to set whatever price it wishes for its product. If it wishes to cut its price in response to generic competition it will generally be free to do so under the section 2 of the Sherman Act as long as that price is not predatory. [203] Generic manufacturers have argued that even the patentee cannot introduce a generic version of its own drug during the 180-day exclusivity period, but courts have rejected that argument. In *Mylan Pharmaceuticals, Inc. v. FDA*, [204] the Fourth Circuit affirmed a district court decision that authorized generics are not subject to the Hatch-Waxman Act's 180-day exclusivity period, and thus may be marketed at the same time that the first true generic is marketed. The Fourth Circuit based its decision entirely on statutory construction and did not discuss antitrust issues.

A patent owner that authorizes a third party to enter as a generic faces a somewhat different analysis, because the agreement is subject to section 1 rather than section 2 of the Sherman Act. Nonetheless, the issues under the rule of reason should be similar. Antitrust law is properly reluctant to condemn agreements that permit additional entry into a market except under unusual circumstances. This is true even though, as here, that entry may create a market failure by underincenting challenges to pharmaceutical patents. An antitrust plaintiff challenging an authorized generic arrangement should have to demonstrate predatory conduct, evidenced by pricing below an appropriate measure of cost or other clear conduct not on the competitive merits designed to exclude a generic competitor.

In *Asahi Glass v. Pentech Pharmaceuticals*, [205] Judge Posner (sitting by designation) approved a settlement between a pharmaceutical company and a generic that authorized that generic to enter, but under unusual and somewhat troubling circumstances. The patentee, Glaxo, had sued Apotex, and Judge Posner had held the patent valid but not infringed, meaning that Apotex could enter the market. Glaxo had also sued Pentech, which made the same product as Apotex and therefore presumably also would not infringe. The parties to the second suit settled with an agreement that Pentech would enter the market as soon as Apotex did, but would exit the

market if and when Apotex exited. Glaxo did not pay Pentech to stay out of the market unless and until Apotex entered but did supply Pentech with the product it would sell when it entered.

This agreement seems designed to discourage entry by Apotex by facing it immediately with generic competition and denying it the benefit of 180-day generic exclusivity. Further, the fact that Glaxo was supplying Pentech suggests that its planned entry may be below cost. Nonetheless, Judge Posner approved the agreement. [206]

The court held that "the general policy of the law is to favor…settlement of patent infringement suits." It found nothing suspicious about this settlement, and worried about the risk of antitrust liability chilling settlements. In so doing, the court set the antitrust bar for settlements quite high, concluding that they were "legal unless a neutral observer would reasonably think that the patent was *almost certain*" to be invalid or not infringed. [207] Judge Posner concluded that that standard was not met in the Pentech suit, even though he had previously held that the patent did not cover the drug in question.

The situation presented in *Asahi* is different and less obviously anticompetitive than in the exclusion payment cases. As Judge Posner noted,

> there is a difference between the reverse-payment case and other forms of settlement. In a reverse-payment case, the settlement leaves the competitive situation unchanged from before the defendant tried to enter the market. In this case, in contrast, the settlement led to increased competition, first in Puerto Rico and now throughout the United States. [208]

This distinction is a fair one. While it may be that the effect of the Glaxo-Pentech agreement was to discourage Apotex from entering the market, courts should be reluctant to find illegal settlements that lead to market entry rather than exit. [209]

Nonetheless, the legal standard the court adopted seems to go too far. The court imported the *Noerr-Pennington* standard of objective baselessness and concluded that Glaxo's suit against Pentech was not objectively baseless even though Glaxo had already lost an identical suit, because it might prevail in the first suit on appeal. But *Noerr-Pennington* protects efforts to file a lawsuit, not agreements among competitors governing how and when they will enter the market. [210] An authorized generic can be predatory and therefore anticompetitive even if the suit the patentee filed was not a sham. Indeed, a pattern of authorized generics at predatory prices across all products may deter generic challenges even if any given patent turns out to be valid.

We think the right analysis is based on predation. Authorized generics should be legal unless they are predatory, as demonstrated either by pricing below cost or by a pattern of conduct not on the competitive merits that is both intended to and actually does deter generics from challenging patents. As with other predation claims, liability should be rare. But a pure predatory pricing claim may be even harder to prove in the authorized generic context. Even where a predatory pricing claim involves patented goods rather than licenses themselves, the economics of patents rarely lend themselves to pricing that is truly below marginal cost. Instead, some cases have involved claims of "limit pricing," or setting a price above costs but sufficiently low that a potential rival cannot recoup its investment. Plaintiffs in the authorized generics cases charge that patentees are deterring generic entry by dropping the price of an authorized generic competitor to a point where generic entry as a whole becomes unprofitable. But the claim is not generally that they are pricing below cost, but that they are depriving a generic challenger of an *above-cost* price reward for bringing the challenge. Doing so may undercut the partial exclusivity promised by the Hatch-Waxman Act to generics who successfully challenge a patent, and thus discourage such challenges in the long run. Nonetheless, courts have not generally been receptive to such claims as long as the price the patent owner or authorized generic charges is above marginal cost. [211] Since that marginal cost is so low, bringing a challenge based on the pure price theory is effectively impossible.

That leaves non-price predatory conduct. Judged by this standard, the *Asahi* agreement raises at least one red flag. The fact that the agreement permitted generic entry only during the period that another generic was in the market, and required the authorized generic to exit the market if and when the competitor was driven out,

suggests both that the purpose in authorizing the generic was to target the competitor and that recoupment of any lost profits was a very real possibility.

15.3a2(B) *Conduct Designed to Eliminate 180-day Exclusivity*

Other conduct by pharmaceutical patent owners may seek to deprive generic challengers of their statutory right to 180-day exclusivity. For example, pharmaceutical patent owners facing a litigation loss have tried to abandon the lawsuit by filing a covenant not to sue, thus depriving the court of jurisdiction to invalidate the patent or hold it not infringed, and therefore deprive the patent challenger of its 180-day exclusivity. Before 2007, courts held that a covenant not to sue deprived the court of subject matter jurisdiction, so that the case had to be dismissed. [212] Even then, courts acknowledged the policy problems dismissal would create:

> Notwithstanding the body of law that mandates dismissal, the court is sensitive to Apotex's argument that Merck is manipulating the court's jurisdiction. Indeed, the court must guard its jurisdiction jealously. Apotex highlights an interesting yet troublesome practice that has emerged from the interplay of the Hatch-Waxman regulatory scheme, covenants not to sue, subject-matter jurisdiction, and the typical time cycle of a patent litigation. This lawsuit exposes the ability of pioneer drug companies to potentially hold generics at bay by suing them, as they are authorized to do when a paragraph IV certification is made in an ANDA, and then granting a covenant not to sue, which divests the court of subject-matter jurisdiction. In this way, district courts can be viewed as unwitting agents in a pioneer drug company's ability to defer competition for as long as possible. As unfortunate as it may be for Apotex, this is the framework that the Hatch-Waxman Act created. The legislative history suggests that, in fact, Congress contemplated the use of covenants not to sue as a means of resolving any controversy created by the filing of an ANDA:
>
> > The provision [a "civil action to obtain patent certainty"]…is intended to clarify that Federal district courts are to entertain such suits for declaratory judgments so long as there is a "case or controversy" under Article III of the Constitution. We fully expect that, in almost all situations where a generic applicant has challenged a patent [by filing an ANDA with a paragraph IV certification] and not been sued for patent infringement, a claim by the generic applicant seeking declaratory judgment on the patent will give rise to a justiciable "case or controversy" under the Constitution. We believe that the only circumstance in which a case or controversy might not exist would arise in the rare circumstance in which the patent owner and brand drug company have given the generic applicant a covenant not to sue, or otherwise formally acknowledge that the generic applicant's drug does not infringe. [213]

In 2007, the Supreme Court rejected the "reasonable apprehension of suit" test for declaratory judgment jurisdiction in *MedImmune Inc. v. Genentech Inc.* [214] In the wake of *MedImmune*, the Federal Circuit recognized this problem, and has permitted declaratory judgment claims challenging pharmaceutical patents even when the patentee has issued a covenant not to sue, so long as the existence of the patent serves as an obstacle to generic entry. [215]

With that path foreclosed, some patent owners have withdrawn or "delisted" patents from the Orange Book in the face of legal challenges to those patents. When they do so, the question arises whether the first ANDA filer is entitled to 180-day generic exclusivity for having forced the patentee to remove the patent through threat of litigation. In *Teva Pharmaceuticals v. Sebelius*, [215.1] the FDA ruled that Teva was not entitled to exclusivity in that circumstance. The D.C. Circuit reversed that conclusion as arbitrary and capricious. While the statute provided for forfeiture of generic exclusivity in a variety of circumstances, the court found that it made no sense to impose forfeiture here.

A final circumstance involving 180-day exclusivity involves claims by the brand owner to be entitled to generic exclusivity. Normally such a claim will not arise, because the brand owner has little incentive to challenge the validity of its own patent in court. But in *Mylan Pharmaceuticals v. Sebelius*, [215.2] the first generic filer,

Teva, purchased the patent owner during the period of a pay-for-delay settlement. When the delay period was ending, Teva asserted that it was entitled to 180-day generic exclusivity as the first filer even though it had not finalized its ANDA or shown an intent to enter the market with a generic drug. Another generic, Mylan, sought an injunction preventing the FDA from granting Teva 180-day generic exclusivity. The court denied the injunction, concluding that while Teva now owned Cephalon (the patent owner), the two were separate corporate subsidiaries and could therefore theoretically be adverse to each other.

15.3b. Deceptive and sham petitioning of regulatory bodies..—Another second form of regulatory gaming achieves its anticompetitive goals through direct manipulation of the regulatory process—the use of deceit or other misconduct to obtain regulatory outcomes that favor the gaming firm. These cases raise tough questions and require courts to strike a tricky balance between regulatory deference and antitrust intervention. The questions here are made more difficult than the settlement cases because the anticompetitive conduct involves the participation (albeit unwitting) of a regulatory agency itself. In particular, the *Noerr-Pennington* doctrine forbids antitrust review of some forms of government petition, even when they may mislead. [216] The doctrine does not, however, require abstention in all cases at all times. [217] In particular, when an agency explicitly relies upon misleading factual submissions by a regulated party, and those submissions materially affect an agency decision that turns out to have exclusionary effects, antitrust law can and does intervene.

15.3b1. Misrepresentations to government price and standard-setting agencies..—The *Unocal* case epitomizes this form of gaming. *Unocal* involved misrepresentations made to the California Air Resources Board (CARB), a state agency charged with reducing fuel emissions. [218] In the late 1990s and early 2000s, CARB conducted a rule-making process to develop specific, stringent standards for low-emissions gasoline. [219] Unocal participated actively in the rulemaking process, advocating a set of standards that closely resembled the ones ultimately adopted by CARB. [220] In its submissions to the agency, Unocal never mentioned that it owned patent rights over the standards; indeed, it repeatedly touted their "flexibility" and "cost-effectiveness," and suggested that it had relinquished any proprietary interest that it might have once had in the standards. [221] In reliance on these representations, CARB adopted the standards, and refiners invested billions of dollars to comply with them. [222] Only then, according to the FTC, did Unocal disclose its newly minted patents and demand royalties for the use of the technology. [223]

Unocal's misrepresentations effectively converted a neutral regulatory process into an exclusionary tool. The purpose of the CARB proceedings was to define a standard that would enable the production of cost-effective, environmentally sensitive fuels—not to give market power to one individual party. Yet Unocal's misrepresentations turned the regulators into unwilling (and unknowing) participants in a scheme to vest Unocal with just such power. According to the FTC, if CARB had known about Unocal's patent rights, it would have either adopted different standards or insisted on more favorable terms of access to the standards by competitors. [224] In other words, the misrepresentations reflect "willful acquisition or maintenance" of power in the fuel market. [225]

From a consumer-welfare perspective, the behavior caused just the kind of harm that antitrust laws seek to prevent—a structural barrier that will inevitably raise prices and cause inefficiently low production in the relevant market. Indeed, the fact that Unocal's conduct was directed at a state agency made competitive harm all the more likely. Other cases have considered misrepresentations to private standard-setting organizations (SSOs). [226] Those representations can facilitate monopolization of an industry, but only if they end up locking an industry into a standard that turns out to be patented. [227] Market participants in private SSOs can choose not to adopt the standard. By contrast, no gasoline company can choose to ignore the CARB standard for reformulated gasoline; if Unocal's misrepresentations or omissions in fact caused the adoption of that standard, companies that wanted to sell gasoline in California had no choice but to pay Unocal whatever it demanded.

The *Discon* case provides another example of this sort of regulatory game. The regulated party in that case engaged in a kickback scheme to deceive regulators into believing that its costs were higher than they really were. [228] The regulators relied on the party's submissions and approved inflated regulated rates, and consumers footed the bill. [229] The Supreme Court appeared almost scornful of the idea that the regulatory fraud could form the basis for an antitrust complaint, declaring that "[t]o apply the *per se* rule here—where the buyer's decision, though not made for competitive reasons, composes part of a regulatory fraud—would transform cases involving business behavior that is improper for various reasons, say, cases involving nepotism or personal pique, into treble-damages antitrust cases." [230] However, because *Discon* involved a very precise legal question—the question of whether to apply per se analysis to the alleged boycott in that case—the Court's dismissive language does not necessarily preclude a rule-of-reason claim based on the same set of facts, but with proof of market power or adverse market impact. [231] And there seems a straightforward theory of competitive harm in this situation.

Despite the obvious competitive harms in these cases, some courts might hesitate to impose liability based on the *Unocal* version of regulatory gaming because of the *Noerr-Pennington* doctrine, which insulates certain government petitions from antitrust liability. Unocal's anticompetitive conduct involved petitioning the government. We think this concern requires careful attention to the facts, but in a case like *Unocal*, it does not justify antitrust abstention.

Under the *Noerr-Pennington* doctrine, "[t]hose who petition the government for redress are generally immune from antitrust liability." [232] The principle applies to all sorts of petitions directed at any branch of government, [233] and it derives from two basic tenets: first, Congress cannot have meant for the Sherman Act to impair citizens' right to participate in our representative democracy; [234] and second, the First Amendment would, in any event, bar such an interpretation. [235] The doctrine seeks to distinguish between commercial activities—which the Sherman Act addresses—and political activities, which lie beyond its reach. [236]

The doctrine, however, has limits. Even in *Noerr* itself, the Supreme Court cautioned that petitioning behavior could lose its protection if it were a "sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor." [237] Since then, the Supreme Court has applied the exception to misrepresentations made to courts and administrative agencies, [238] including patent-infringement suits based on a patent obtained through fraud. [239] The cases following *Noerr* seem to distinguish between attempts to influence a legitimate government process, on the one hand, and behavior that shatters the integrity of the process and effectively converts it into a private affair, on the other.

While a full analysis of the *Noerr-Pennington* exemption falls beyond the scope of this chapter, [240] we think the *Noerr-Pennington* doctrine must give way when a defendant has co-opted an administrative process through material misstatements or other fraud. When this happens, the defendant is not merely exercising its rights to influence a legitimate government process; it is effectively converting the process into a private vehicle to exclude competition. [241] As the FTC concluded in *Unocal*, "deliberate misrepresentations that substantially affect the outcome of a proceeding or so infect its core to deprive the proceeding of legitimacy may not, in appropriate circumstances, qualify for *Noerr–Pennington* protection." [242]

15.3b2. Misrepresentations to the FDA; Sham Petitions that Regulate Entry

(A) *Orange Book Listings*

A separate disclosure issue involves representations made not to a government standard-setting organization or to the PTO, but to the Food and Drug Administration. As the Hatch-Waxman Drug Price Competition Act has been implemented, a pharmaceutical company that owns a patent it claims covers a particular drug lists

that patent and the corresponding drug in the FDA's "Orange Book." A prospective generic manufacturer who wants to make a drug that may be covered by a patent files an abbreviated new drug application (ANDA) with the FDA. If the drug in question is listed in the Orange Book, the FDA notifies the patentee of the ANDA. If the patentee files an infringement lawsuit against the generic manufacturer, [243] the FDA cannot proceed to consider the ANDA for 30 months, unless a court issues an opinion during that time holding the patent invalid. [244] In effect, the FDA acts as though the patent were conclusively presumed valid unless the Federal Circuit instructs it otherwise. The effect of this rather remarkable rule is to delay drug price competition for several years even where a patent is clearly invalid, by granting what is akin to an automatic preliminary injunction whenever a pharmaceutical patent owner files suit against a generic manufacturer. The Federal Circuit has held that district courts have no power to shorten the 30-month stay before the lawsuit is resolved, even where the court believes the patent is clearly invalid. [245] Indeed, in *Andrx* the Federal Circuit held that listing a new patent covering the same drug in the Orange Book started a new 30-month stay running, suggesting that the possibility for delaying competition may extend much further than 30 months. [246]

Until 2004, generic drug manufacturers had no recourse except antitrust law against the practice of "evergreening" patents by listing multiple dubious patents in the Orange Book, because the courts had held that there was no right to challenge the FDA's ministerial addition of a patent to the Orange Book. [247] But legislative changes effective in 2004 deal with the problem of evergreening, both by giving a generic ANDA applicant sued for patent infringement the right to assert a counterclaim challenging the listing of information in the Orange Book and by limiting patentees to a single 30-month stay for any given drug, regardless of the number of patents listed as covering that drug. [248] The result is that while antitrust challenges to past evergreening efforts will continue, there are unlikely to be new cases brought on the basis of continuing conduct.

There may still be cases based on fraudulent listing of an original patent in the Orange Book, however. Such a challenge was at issue in *Caraco Pharmaceutical Labs v. Novo Nordisk*. [248.1] The issue in that case was whether a method patent was properly listed on the Orange Book if it covered just one of multiple possible uses for a drug, even though the generic in that case sought to use a different method. The Federal Circuit held that it did, [248.2] but the Supreme Court reversed. The Court held the generic could bring a claim for correction of the Orange Book where the patent was properly listed on the Orange Book but the listing should be narrowed to exclude the generic's noninfringing use. The Court did not directly opine on antitrust matters, but it did characterize the use of overbroad listing codes in the Orange Book as "anticompetitive." [248.3]

A number of generic pharmaceutical companies and antitrust enforcement agencies have challenged the allegedly fraudulent listing of patents in the Orange Book. *In re Buspirone Patent Litigation* [249] held that a pharmaceutical patent owner was not entitled to *Noerr* immunity for the act of listing its patent in the FDA's Orange Book because the FDA had no discretion to refuse to list the patent. The court concluded that the First Amendment rationale for *Noerr* immunity was implicated only when "the government acts or renders a decision after an independent review of the merits of a petition," not when "the government acts merely in a ministerial or nondiscretionary capacity in direct reliance on the representations made by private parties." [250]

A purely ministerial government decision generally does not enjoy the *Noerr-Pennington* antitrust immunity for petitions to government agencies. Under *Noerr-Pennington* generally, a private firm cannot be found to violate the antitrust laws for requesting the government to approve or engage in anticompetitive conduct when the injury results from the government's granting of the anticompetitive request. But often the government's "grant" of a petition amounts to no more than a rubber stamp of the private firm's request. For example, many regulated firms are required to file "tariffs" with the government stating their rates, terms of service, and other important information pertaining to their price and output. Although some agencies actively review tariff filings and disapprove many or seek modification, often the agency does little more than file the tariff document, automatically approving it, or in some cases examining it only upon complaint. The courts routinely hold that tariff

filings under such circumstances are not protected "petitions" to the government because the government plays no role as decision maker. [251] The *Buspirone* court said:

> [T]he *Noerr-Pennington* doctrine is not applicable to conduct through which private parties seek to achieve anticompetitive aims by making representations to the government in circumstances where the government does not perform any independent review of the validity of the statements, does not make or issue any intervening judgment and instead acts in direct reliance on the private party's representations.…
>
> Thus, listing [in the Orange Book] is much more like the filing of a tariff than the kind of conduct through which private parties seek to influence governmental decision making and that has traditionally been immunized under the *Noerr-Pennington* doctrine. [252]

Or as another court said,

> it is paramount to keep in mind that the FDA, in deciding to make an Orange Book listing, is not acting as a patent tribunal. It has no expertise—much less any statutory franchise—to determine matters of substantive patent law. In making its decision to list a patent, therefore, it is entirely appropriate and reasonable for the FDA to rely on the patentee's declaration as to the coverage. [253]

The court denied *Noerr-Pennington* immunity to the act of *registering* a patent in the Orange Book. The act of filing an infringement suit based on that patent is an entirely different matter because in hearing an infringement claim the federal district court is clearly acting as an active decision maker, and the right to plead in court is at the heart of *Noerr-Pennington* protection.

By contrast, where a drug company petitions the FDA to do something more than a ministerial act, *Noerr* immunity will apply. Thus, in *In re Tamoxifen Citrate Antitrust Litig.*, the court immunized an argument to the FDA by a settling generic manufacturer that it should be entitled to keep its 180-day exclusivity notwithstanding its failure to market a generic version of the drug. [254] Unlike Orange Book listing, the generic manufacturer in *Tamoxifen* was making a substantive argument for the FDA to make a legal ruling, triggering *Noerr* protection for the petition.

Denying *Noerr* immunity for false Orange Book listings does not, of course, mean that the challenged conduct is necessarily illegal. But it does mean that it will be evaluated on the merits. Nor should the fact that there is a regulatory structure justify antitrust deference. In *In re Remeron Antitrust Litig.*, [255] the court confronting an Orange Book false listing case rejected the defendant's argument that active and comprehensive agency regulation of the kind that the Supreme Court had found to exist under the Telecommunications Act in *Verizon Communications v. Law Offices of Curtis V. Trinko*, [256] served to attenuate antitrust concerns. The court noted:

> In *Trinko*, the statutory subject was the Telecommunications Act of 1996, which is a complete regulatory scheme that grants regulators significant power to enforce rules and to issue penalties. By contrast, the FDA regulators have (and choose to exert) significantly less authority over Orange Book listings because the Hatch-Waxman Act places the power to decide which patents to list on the private company that holds the NDA. [257] The FDA, in a December 12, 2000 brief regarding the listing of the drug BuSpar, explained its role in the Orange Book process:
>
> > [T]he FDA's mission is to protect the public by ensuring that drugs are safe and effective. Congress did not intend FDA to divert its attention from this mission by spending enormous resources attempting to resolve economic disputes about the coverage of patent claims. For this reason, Congress explicitly required FDA to publish patent information upon its submission, and for any such disputes…to be resolved by private litigation. [258]

The *Buspirone* court then considered whether a *Walker Process*-style antitrust claim [259] could lie for fraudulent filing of an Orange Book patent:

> Neither the Supreme Court nor the Court of Appeals for the Federal Circuit has addressed whether the *Walker Process* exception would apply to a fraudulent listing of a patent in the Orange Book along with subsequent lawsuits seeking to exploit the listing for anticompetitive advantage. However, in creating the *Walker Process* doctrine, the Supreme Court explained that a claim alleging an initial fraud on the Patent Office would avoid *Noerr-Pennington* immunity for a number of reasons that are directly applicable to fraudulent listings in the Orange Book. In particular, the Court explained that:
>
> > [a] patent by its very nature is affected with a public interest.…[It] is an exception to the general rule against monopolies and to the right to access to a free and open market. The far-reaching social and economic consequences of a patent, therefore, give the public a paramount interest in seeing that patent monopolies spring from backgrounds free from fraud or other inequitable conduct and that such monopolies are kept within their legitimate scope.
>
> Because a private party can effectively extend a patent monopoly by listing a patent in the Orange Book and then filing suit against generic competitors in that context, these same considerations apply to this conduct. [260]

The Hatch-Waxman regulations provide unscrupulous patent owners with a powerful tool for excluding competitors by compelling the FDA to deny or delay approval for new generic drugs. If a patentee invokes that mechanism by listing either a clearly invalid patent or one that obviously does not cover the drug claimed, and the effect is to permit the patentee to acquire or maintain market power, the abuse of the FDA process should be actionable under § 2.

Courts have also found *Noerr-Pennington* immunity not to apply when patent owners use the interplay between patent law and Hatch-Waxman to evergreen their patents, notwithstanding the fact that granting a patent does involve more than a ministerial act. In *In re Neurontin Antitrust Litigation*, [260.1] the court held that an alleged scheme to extend patent life by filing and then dismissing continuation applications in the PTO in order to obtain multiple 30-month stays of ANDA approval could violate the antitrust laws. Taken as a whole, the scheme could "reasonably be considered nothing more than an attempt to interfere directly with the business of Warner-Lambert's generic competitors," and hence exempt from *Noerr* immunity.

Allegations of false representations to the FDA might also give rise to a patent misuse defense. [261] While *C. R. Bard v. M3 Sys.* cautioned against expanding patent misuse into a general doctrine of wrongful use, [262] allegations of this sort are merely new twists on classic efforts to cartelize markets or employ regulatory barriers to exclude competition. Courts should have no trouble analyzing them under misuse principles.

A final Orange Book petition case involves efforts by a patentee to *delist* a patent in the Orange Book, typically to deprive an about-to-be-successful generic challenger to the patent from prevailing and therefore obtaining 180-day exclusivity. The FDA issued a regulation providing that if the patented was delisted from the Orange Book, a generic was no longer entitled to 180-day exclusivity because it had not invalidated a listed patent. The D.C. Circuit reversed, holding that the FDA's interpretation of the statute was impermissible. [263]

(B) *FDA Citizen Petitions*

A separate issue concerns not Orange Book listings but sham citizen petitions to the FDA. Citizen petitions to the FDA have been on the rise in recent years, particularly those filed by branded drug companies against generic drugs. [263.1] Carrier and Wander find that the vast majority of brand petitions against generic (81%) are ultimately rejected. Because the FDA historically could not approve a drug while a citizen petition is pending, the use of those petitions has delayed generic entry in a number of high-profile cases. Congress showed sensitivity to this concern, enacting section 505(q) of the Federal Food, Drug and Cosmetic Act in 2007 to limit that delay. [263.2] That section requires the FDA to deny any petition it determines was intended to delay competition,

requires rapid resolution of citizen petitions, and forbids the FDA from delaying approval of an ANDA based on a pending petition unless "a delay is necessary to protect the public health." [263.3]

Unlike Orange Book listings, which are not entitled to *Noerr* immunity because they are effectively private acts that simply take place before the government, a citizen petition asks the FDA to take substantive action. Because it is the FDA's discretionary action that gives rise to plausible antitrust harm, *Noerr* should immunize those petitions unless they are shams. [264]

In *Louisiana Wholesale Drug Co. v. Aventis Pharmaceuticals*, [265] the plaintiff alleged that a pharmaceutical patent owner filed sham citizen petitions with the FDA in an effort to delay the approval of generic manufacturer's ANDA (abbreviated new drug application) petitions. The FDA ultimately rejected the Petition as "unfounded," but its existence delayed regulatory approval of the generic drug and therefore delayed market entry. The court found that the sham allegation presented a triable issue of fact regarding whether the *Noerr* immunity standard had been met. The court later also denied defendants' motion for summary judgment. [266] But at trial, the jury found that the petition was not a sham, and the district court refused to disturb that verdict, noting that the petition in question presented a novel issue to the FDA. [266.1] Other cases have found branded drug citizen petitions to be shams and accordingly permitted antitrust claims to proceed. [266.2]

The FDA itself has taken notice of the practice of filing sham citizen petitions. Section 505(q)(1)(E) of the Food, Drug & Cosmetics Act provides that an FDA petition may be denied when it "was submitted with the primary purpose of delaying the approval of an application and the petition does not on its face raise valid scientific or regulatory issues." In a 2013 ruling, the FDA rejected a petition to delist a form of a drug about to face generic competition for purported safety reasons. The FDA found no safety-related reason to delist the drug. It commented on the fact that the patentee was still selling the supposedly-unsafe form until such time as it could complete a switch to a different (and still-patented) form. While the FDA did not hold the petition to be a sham, it did refer the matter to the Federal Trade Commission to investigate. [266.2.1]

Filing a sham citizen's petition can delay generic entry and accordingly restrict competition. For that to be true, however, the generic must have been able to enter but for the petition. Accordingly, the D.C. Circuit has held that the generic must show that it was prepared to enter the market and intended to do so but for the defendant's conduct. [266.3] If the FDA would not have approved the generic's ANDA in any event, the sham citizen's petition cannot be the cause of entry delay. [266.4] By contrast, where the FDA approves the ANDA on the same day it denies the citizen petition, it is reasonable to conclude that it delayed the ANDA approval until the petition was resolved, at least for petitions filed before September 2007 or which assert a relationship to public health. [266.5] Nonetheless, courts have not required proof that the FDA definitely would have approved the petition; an expectation of success is sufficient. [266.6]

15.3c. Unilateral Conduct

15.3c1. "Product Hopping"; Design Changes

Pharmaceutical patent owners have engaged in a second form of evergreening, one that might be described as "product-hopping." Product-hopping pharmaceutical companies faced with the possibility of generic competition once a patent expires or is held invalid sometimes make trivial alterations to their approved drugs, get FDA approval for those trivial alterations, and then replace the old product with the new product. For example, a patentee might switch from selling a drug in capsule form to selling the same formulation of the same drug in tablet form. While the change won't matter much to consumers, it can be sufficient to require a generic company to start the ANDA filing process over from scratch, delaying the date of generic entry and triggering an entirely new round of patent litigation.

Generally, to introduce a new drug to market a pharmaceutical company must provide direct evidence of its safety and efficacy, and, upon approval, it must also provide a listing of any relevant patents in the FDA's Orange Book. [267] The Hatch-Waxman Act, which Congress passed in 1984, expedites the approval process for generic follow-on drugs. [268] Rather than submitting full safety and efficacy data, a generic manufacturer can obtain FDA approval by filing an Abbreviated New Drug Application (ANDA), which certifies the bioequivalence of its generic and an existing branded drug. [269] The statute requires the FDA to complete its review within 180 days, [270] but the process often takes longer. [271] Once approved, the generic receives an "AB-rating," which allows pharmacists to substitute the generic when presented with a prescription for the branded product. [272] Because the patented pharmaceutical is now being sold only in the new tablet formulation, the generic company will be unable to rely on generic substitution to sell its ANDA-approved capsules.

A number of antitrust challenges to product-hopping have recently been decided or are pending as of this writing. [273] Because product changes by pharmaceutical patent owners represent unilateral conduct, they are evaluated under section 2 of the Sherman Act. A pharmaceutical patent owner has no legal duty either to help its generic competitors or to continue selling a particular product. Patent owners may argue with some justification, therefore, that they cannot be held liable for stopping the sale of a product. At the same time, product-hopping seems clearly to be an effort to game the rather intricate FDA rules to anticompetitive effect. [274] The patentee is making a product change with no technological benefit solely in order to delay competition. Under the analysis we offer in § 12.3e3, such a change could qualify as a predatory product change if it lacks substantial medical benefits.

In *Abbott Labs v. Teva Pharmaceuticals*, [275] the court faced such a claim as a matter of first impression. Teva, a generic pharmaceutical manufacturer, alleged that Abbott engaged in a pattern of excluding generic substitutes for TriCor by making a series of changes to its product timed to prevent Teva from introducing a generic substitute. Teva alleged that the changes were of little or no medical value (one change was from capsules to tablets, and another reduced the active amount of the drug slightly), and that the changes were made just as Teva was poised to introduce a generic substitute. Further, Teva alleged that Abbott not only changed its product but bought up and destroyed its old products and listed them as obsolete in a national drug database. As a result, Teva argued, while it was able to enter the market and sell its drugs, it could not take advantage of state generic substitution laws, because Abbott's changes prevented Teva's drug from being equivalent and required it to start over in seeking FDA approval for the modified drug.

Abbott moved to dismiss Teva's antitrust claims, and the district court denied the motion. The court noted that it "faces a difficult task when trying to distinguish harm that results from anticompetitive conduct from harm that results from innovative competition." [276] Nonetheless, the court concluded that rule of reason treatment was appropriate in this instance without any special deference to the defendant's product changes, since the allegations were that those product changes wouldn't face market competition because of regulatory barriers:

> The nature of the pharmaceutical drug market, as described in Plaintiffs' allegations, persuades me that the rule of reason approach should be applied here as well. The per se standard proposed by Defendants presupposes an open market where the merits of any new product can be tested by unfettered consumer choice. But here, according to Plaintiffs, consumers were not presented with a choice between fenofibrate formulations. Instead, Defendants allegedly prevented such a choice by removing the old formulations from the market while introducing new formulations. Hence, an inquiry into the effect of Defendants' formulation changes, following the rule of reason approach, is justified.…
>
> Therefore, in this case, an antitrust inquiry into the benefits provided by Defendants' product changes is appropriate. Contrary to Defendants' assertion, Plaintiffs are not required to prove that the new formulations were absolutely no better than the prior version or that the only purpose of the innovation was to eliminate the complementary product of a rival. Rather, as in *Microsoft,* if Plaintiffs show anticompetitive

> harm from the formulation changes, that harm will be weighed against any benefits presented by Defendants. [277]

Because Teva had alleged that the product changes were not significant improvements and were not cost-justified, its allegations survived the motion to dismiss. [277.1]

Abbott also argued that because Teva was free to sell the old formulation of TriCor, Abbott's product changes could not have had an anticompetitive effect. The court rejected that claim as well:

> To show that conduct has an anticompetitive effect, "it is not necessary that all competition be removed from the market. The test is not total foreclosure, but whether the challenged practices bar a substantial number of rivals or severely restrict the market's ambit." [278] Competitors need not be barred "from all means of distribution," if they are barred "from the cost-efficient ones." [279] Here, while Teva and Impax may be able to market their own branded versions of the old TriCor formulations, they cannot provide generic substitutes for the current TriCor formulation, which is alleged to be their cost-efficient means of competing in the pharmaceutical drug market. That opportunity has allegedly been prevented entirely by Defendants' allegedly manipulative and unjustifiable formulation changes. Such a restriction on competition, if proven, is sufficient to support an antitrust claim in this case. [280]

Contrast *Abbott* with *Walgreen Co. v. AstraZeneca Pharmaceuticals*. [281] In that case, the plaintiffs alleged that once the patent for Prilosec expired, the patent owner sought to switch the market to its next-generation (and still-patented) alternative, Nexium, by ceasing its marketing efforts for Prilosec and investing substantial resources in marketing Nexium to doctors. But unlike Abbott, AstraZeneca did not withdraw Prilosec from the market or seek to prohibit generic substitution of Prilosec. The court held that this conduct did not violate section 2: "Advertising that emphasizes a producer's strengths and minimizes its weaknesses does not, at least unless it amounts to deception, constitute anticompetitive conduct violative of section 2." [282] The court distinguished *Abbott*, noting that in *Abbott* the defendant's conduct had reduced consumer choice by withdrawing a product from the market, while "AstraZeneca added choices" by introducing Nexium. [283]

We think the *Abbott* and *Walgreen* courts draw the correct distinctions. Product hopping takes advantage of the lag times inherent in the FDA's generic-approval process. Before 2004, firms could extend their exclusivity for a product almost indefinitely, by adding new patents to their Orange Book filings and stacking up consecutive thirty-month stays. [284] After Congress corrected that particular problem, crafty firms took a different tack: rather than stacking patents, they stacked products—making trivial changes to their product formulation and pulling the old drug from the market. This product hopping delays generic competition in two ways. First, like the earlier forms of evergreening, product hopping can prompt a whole new set of Orange Book filings, ANDA Paragraph IV certifications, and litigation-triggered thirty-month stays. Second, even without new patent claims, product hopping delays generic substitution for the new branded product because the generic firm must file a second ANDA, which faces the same lengthy FDA review as the first one. The generic firm may, of course, continue to offer the first drug, for which it already gained approval. That means little, however, if the branded firm has pulled that drug from pharmacy shelves and convinced doctors to write prescriptions for its new product. Until the ANDA for that new product is approved (with its AB-rating), state laws limit the ability of pharmacists to substitute the "old" generic for the "new" branded drug. [284.1]

Pharmaceutical product hopping presents a paradigmatic case of a regulatory game. Without the FDA's product-approval framework, generic firms could quickly go to market with competing versions of branded drugs upon expiration of a patent—or even earlier, when they have confidence that their product does not infringe any valid patent on the drug. But the lengthy product-approval process—combined with the two-and-a-half-year automatic stay that follows any patent suit—acts as a barrier to such competition. While that barrier may or may not be a necessary cost of accommodating patent rights and health-and-safety concerns, product hopping exploits the product-approval process precisely because of its exclusionary effects and converts it into a tool for suppressing

competition. Making matters worse, the regulators in these cases can do nothing to thwart this obvious abuse of their administrative function. And while Congress, the FDA, or states could theoretically address the problem prospectively by allowing generic substitution across formulations, [285] such an ex post solution would neither compensate for past harm nor deter new variations of the regulatory game.

From an antitrust perspective, product hopping to ward off generic competition is precisely the sort of behavior the Sherman Act condemns. While monopolists have no general duty to help their competitors, they do have an obligation to refrain from acts that have no purpose or effect except to exclude competition. [286] And while distinguishing between the two can be tricky, courts have proven themselves up to the task, even in cases involving product design. [287] It makes no sense to immunize patently anticompetitive behavior because of the risk that some cases might prove tough to decide. The proper standard requires deference to innovation, but not complete abdication.

The district court in the *Abbott Labs* case—following the analytical structure established in the D.C. Circuit's *Microsoft* opinion—outlined what we view as a reasonable approach to the product-hopping problem. [288] The court applied antitrust law to the gaming behavior, rather than washing its hands of the case because of its regulatory context. On the merits, the court applied the rule of reason, first requiring plaintiffs to show that the defendant's product changes had an anticompetitive effect. [289] The court held that plaintiffs had met their burden (at least in the context of a motion to dismiss) by alleging that Abbott's change in formula, paired with its abandonment of the old drug, blocked plaintiffs from "their cost-efficient means of competing in the pharmaceutical drug market," thereby harming both plaintiffs and consumers. [290] The court suggested that defendants could rebut the showing of competitive harm by establishing a valid business reason for the behavior. [291] "[I]f such a justification were offered, the plaintiff could rebut it or, alternatively, establish antitrust liability by demonstrating that 'the anticompetitive harm of the conduct outweighs the procompetitive benefit.'" [292]

By contrast to *Abbott*, *Walgreen* represents a case in which the patentee introduced a new product but did not take advantage of the regulatory scheme to interfere with the introduction of a generic drug by the patent challenger. Because *Walgreen* does not game the regulatory system, the antitrust risks are substantially less. If the generic lost market share in that case, it is more likely because of the desirability of the patent owner's new product, which is now competing head to head with the generic product.

The product-hopping problem could be solved if the FDA Act permitted generic substitution across formulations. In the absence of such a statutory change, antitrust cases will continue to arise.

15.3c2. *Product bundling*..—A variant of product-hopping that has yet to be litigated in its pure form involves the bundling of two drugs, one with patent protection and one without, into a single cocktail. Changing from a single drug to a multi-drug cocktail presents issues similar to changing the formulation of a single drug, and we think the antitrust analysis should be similar to the one we just outlined. A court should not hesitate to find such conduct anticompetitive if the cocktail lacks significant medical benefits over the single drugs alone, if they are sold only in cocktail form and if timed to coincide with the expiration or invalidation of a patent. On the other hand, combining drugs can have significant medical effects, and as discussed in Chapter 12, courts should show some deference when faced with evidence of significant medical benefit. [293] And if the patent owner continues to offer the original drug alone, rather than making the cocktail the only option, we think the *Walgreen* approach is the correct one.

A variant of product bundling was at issue in the *Norvir* litigation. Because the *Norvir* claims involved price squeezes rather bundling alone, we discuss them in the next section.

15.3d. Regulation and price squeezes..—A price squeeze occurs when a vertically integrated firm with a regulated monopoly in an upstream market faces competition in a downstream market, and the firm compresses its wholesale and retail prices to make it impossible for others to compete with it in that downstream (retail) market. [294] If the wholesale price is high enough and the retail price low enough, competing retailers simply

cannot cover their costs and will be driven from the market. In *Pacific Bell v. linkLine*, [295] for example, an integrated firm allegedly charged its retail competitors wholesale prices that actually exceeded its own retail rates. [296] A competitor obviously could not stay in the market for long when the cost of a single input is higher than the price it can charge consumers for its overall product.

The economics of price squeezes are the subject of some debate. Advocates of a "one monopoly profit" theory contend that price squeezes can cause no harm, because the upstream monopolist cannot raise the price any more by controlling two levels of production than it could by controlling only the upstream market. [297] Others, however, take issue with the one-monopoly-price theory and contend that monopolists can both increase their profits and insulate their economic power by leveraging their monopoly into related downstream markets. [298] Further, price squeezes can affect non-price aspects of a product such as quality, service, or innovation.

Whatever the economics of price squeezes more generally, most courts and commentators seem to agree that one form of price squeeze does raise antitrust concerns: a price squeeze involving *predatory* prices at the retail level. [299] In particular, when a monopolist lowers its retail prices to below its relevant measure of costs, it can face claims of predatory pricing like any other established or aspiring monopolist. [300] Predatory pricing alone can be illegal if the monopolist is likely to be able to recoup its costs. But the existence of a price squeeze by a monopolist can help ensure the success of predation as an exclusionary tactic. And if the monopolist is compensated for its regulated wholesale prices, such regulation can also help the monopolist recoup its losses.

Price squeezes can, depending on the circumstances, involve a regulatory game. Price squeezes can occur in fully regulated markets (with regulated prices at both wholesale and retail levels), partially regulated markets (with regulated wholesale prices, but no regulation at the retail level), and unregulated markets. And while their use in fully regulated markets probably lies beyond the jurisdiction of antitrust courts, [301] partially regulated price squeezes raise thornier questions. If, for example, a partially regulated firm convinces regulators to approve an unreasonably high wholesale price for an input that it controls, it can easily undercut its retail rivals, who must pay the wholesale price as a part of their cost of production. If the cost-cutting is predatory, the regulated party can effectively drive out its retail competition, which perverts the entire purpose of the wholesale price regulation —ensuring meaningful access to the input for competitors.

Yet even this form of predatory price squeeze raises difficult questions that lie at the very intersection of regulatory deference and substantive antitrust law. In particular, because predatory-pricing claims require proof that a defendant priced below its costs, courts must consider the relationship between the regulated wholesale prices and the “appropriate measure” of a defendant's costs. [302] Because the defendant controls the plaintiff's costs in a price squeeze, ordinary predatory-pricing case law may not fully capture the anticompetitive effects of the behavior. An alternative understanding of the practice could condemn behavior designed to raise rivals’ costs in order to exclude equally efficient rivals. [303] In the context of vertical integration, though, an antitrust plaintiff still needs a theory of why the defendant would be motivated to squeeze out the downstream competitor.

Whatever the economic merits of treating price squeezes differently than ordinary predatory pricing, the Supreme Court in *linkLine* flatly rejected the idea. The *linkLine* case involved an alleged price squeeze in the digital subscriber line (DSL) Internet-services market, a partially regulated industry. [304] According to linkLine, Pacific Bell not only compressed its wholesale and retail prices, but, for a period, it charged other DSL providers wholesale prices that exceeded the fees charged to retail customers. [305] If true, such a price structure would obviously make it impossible for competitors to buy DSL access and resell it in competition with Pacific Bell. The Ninth Circuit held these allegations sufficient to state a claim for monopolization even in the absence of predation. [306]

The Supreme Court reversed. Writing for the majority, Chief Justice Roberts first invoked *Trinko* for the proposition that a defendant with no antitrust duty to deal has absolute control over the terms—if any—on which

it does business with its rivals. [307] Given that, the Court held that linkLine could not challenge Pacific Bell's wholesale prices. The retail prices, on the other hand, could be challenged, but only if they met the *Brooke Group* requirements for predatory pricing: below-cost pricing and a "dangerous probability" that the defendant could recoup its investment in pricing below costs. [308] Because the complaint on appeal had not alleged predatory pricing, the Court found it legally insufficient.

By rejecting the price squeeze theory in the absence of either a duty to deal or predatory pricing, the *linkLine* Court sounded the death knell for price squeezes as standalone antitrust claims. Going forward, price squeeze plaintiffs in both regulated and unregulated industries must allege either a duty to deal or *Brooke Group*-type predatory pricing. Perhaps ironically, a resort to regulatory deference in *linkLine* could have resulted in a narrower opinion that preserved the plausibility of price squeeze claims in other, unregulated contexts. Justice Breyer, in concurrence, would have opted for that approach. [309] Rather than shoe-horning all price squeeze claims into refusal-to-deal standards, Justice Breyer would have rejected the plaintiff's claims because they rested on a challenge to regulated rates:

> We have before us a regulated firm.… And, in my view, a purchaser from a regulated firm (which, if a natural monopolist, is lawfully such) cannot win an antitrust case simply by showing that it is 'squeezed' between the regulated firm's wholesale price (to the plaintiff) and its retail price (to customers for whose business both firms compete). When a regulatory structure exists to deter and remedy anticompetitive harm, the costs of antitrust enforcement are likely to be greater than the benefits. [310]

While *linkLine* addresses the general validity of price squeeze claims, it leaves many details unresolved. In particular, while the Court confirms that predatory price squeeze claims must satisfy the *Brooke Group* requirement of below-cost pricing, *Brooke Group* itself fails to define what "costs" mean. Particularly in cases involving regulated wholesale rates, courts will have to decide whether—and to what extent—the wholesale numbers are relevant to the appropriate measure of costs. Should courts treat the regulated prices as an accurate measure of the cost of the regulated input and assume that retail prices that fall below them are by definition predatory? Should courts instead treat the regulated wholesale price as irrelevant and require direct evidence of the integrated firm's overall costs? Or, at the other extreme, should courts decide that antitrust laws have no role to play because of the existence of regulation at one level of production?

We can see good reasons to support either of the first two approaches to predatory-price-squeeze claims. While it seems reasonable to hold a producer to what it tells regulators about its accurate measure of cost, the wholesale rates do not necessarily reflect the producer's cost of utilizing the wholesale input internally; it may well cost more to provide it to third parties. [311] On the other hand, courts may find the regulated rate useful as a benchmark to evaluate the credibility of the cost evidence provided by the parties. [312]

The third option, however—complete abdication of antitrust law's role in a partially regulated industry—makes no sense as a matter of law or economic policy. In the (probably rare) case in which an integrated firm engages in true predatory pricing, its behavior can undermine competition in the retail market just like other forms of predatory conduct. Indeed, as with standard setting, the fact of regulation may make the conduct more problematic than it would be in the absence of regulation, because the monopolist can rely on a government-approved wholesale price to compel payment by retail competitors and therefore create the price squeeze. And the regulators in these cases have no power to address the exclusionary behavior because their jurisdiction is limited to the wholesale—rather than the retail—price.

Of course, a predatory-pricing claim requires proof of other elements as well—evidence of actual or potential monopoly power in the relevant (in this case, retail) market, as well as a likelihood of recoupment should the scheme succeed in driving competitors from the market. As a result, we think successful predatory-price-squeeze claims—like predatory-pricing claims more generally—are likely to be rare. Their rarity, however, appropriately owes itself to stringent standards of substantive antitrust law, rather than absolute deference to regulators in even partially regulated markets.

Several cases have been filed regarding Abbott's marketing of the patented AIDS drug Norvir alone and in conjunction with other protease inhibitors whose patents have expired. Those cases present an allegation that Abbott raised the price of its patented drug standing alone in order to make its patent-generic drug cocktail more attractive by comparison, and therefore to dominate the market for that combination despite the ability of generic companies to sell the complementary protease inhibitor. In *Schor v. Abbott Labs*, [313] the Seventh Circuit dismissed the complaint for failure to state a claim, refusing to accept monopoly leveraging as a valid theory of antitrust harm and finding that the plaintiff had not stated a claim of a tying arrangement. Indeed, the court found the allegations implausible as a matter of economic theory: "Abbott's profits are highest when the price of other protease inhibitors is lowest, and Abbott therefore has a powerful incentive to encourage competition among other producers rather than monopolize the market for all protease inhibitors." [314]

By contrast, a district court in California had found that the same claims (filed there by a class of purchasers) were sufficient to survive summary judgment. [315] It noted that the Ninth Circuit, unlike the Seventh, permitted claims for monopoly leveraging. [316] But the Ninth Circuit reversed in view of *Pacific Bell Telephone Co. v. linkLine Communications, Inc.*: [317]

> Applying *linkLine* leads us to conclude that Does' claim falls short as well. They allege no refusal to deal at the booster level, and no below cost pricing at the boosted level. Does try to distance themselves from *linkLine* on the footing that their claim is for monopoly leveraging, not price squeezing, and that Abbott provides products to consumers in both the booster and boosted markets whereas AT&T provided products in retail and wholesale markets. We understand the difference, but it is insubstantial. However labeled, Abbott's conduct is the functional equivalent of the price squeeze the Court found unobjectionable in *linkLine*. Abbott sells Norvir as a standalone inhibitor and as part of a boosted inhibitor instead of selling Norvir to its competitors at a high price for use with their own protease inhibitors while attributing a lower price to the product when used as part of its own boosted inhibitor. Either way, the alleged vice is that Abbott is using its monopoly position in the booster market to raise the price of Norvir while selling its own boosted inhibitor at too low a price. And either way, this puts the squeeze on competing producers of protease inhibitors that depend on Norvir for their boosted effectiveness and consumer acceptance. [318]

The court declined to reach the question of predatory pricing because it was not raised below. It also concluded that monopoly leveraging, at least in the context of a price squeeze, could not survive *Pacific Bell*. [319]

Nonetheless, the district court in a related case, *Safeway, Inc. v. Abbott Laboratories* [320] found that the plaintiffs had adequately pled a predatory pricing claim based on bundled discounting. The defendant sold a patented drug, Norvir, at a very high price, but sold the drug in combination with another at a low price, such that, when the discount is attributed across the two products, the second product was being sold below cost. And under the Ninth Circuit test in *Cascade Health Solutions v. PeaceHealth*, [321] the plaintiff in such a case need not show a dangerous probability of recoupment.

Footnotes

78 See, e.g., *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.* , 350 F.3d 1181 (11th Cir. 2003). When Zenith and Geneva each began programs to produce a generic equivalent of a pharmaceutical patented by Abbott, Abbott claimed infringement. *Id.* at 1344. It settled both suits, paying Zenith $3 million and Geneva $4.5 million each month for their promise to stay out of the market. *Id.* at 1346. The district court's finding that this payment was illegal per se was reversed by the Eleventh Circuit. Compare *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003) (finding per se illegality on facts similar to Valley Drug). We intend the term "exclusion payment" to include situations in which the defendant, often a generic pharmaceutical company, never has an opportunity to enter the market, and is paid not to enter, as well as situations in which the defendant is paid to exit a market in which it already competes.

79 Cf. *Intel Corp. v. United States Intl. Trade Commn.*, 946 F.2d 821, 826 (Fed. Cir. 1991) (involving Intel, which owned a patent on a processor chip but hired Sanyo as its "foundry," or "subcontractor," to produce chips under its license).

Uncertainty about the outcome of an infringement suit might also incline the patentee to settle, either by accepting a royalty in exchange for a license or else by making a payment in exchange for the infringement defendant's exit. Under perfect information, the differences between the two types of agreements tend to dissolve. For example suppose that a patent is worth $1 million per year as long as it excludes everyone, and there is a 60 percent chance that the infringement claim will prevail. In that case that patentee would be willing to pay some amount up to the present value of $400,000 per year to obtain an agreement from the infringement defendant that it not enter the market. The patentee could obtain precisely the same value by a license agreement given to the infringement defendant, whose value makes the joint production of the two firms worth $600,000 a year to the patentee. In either case the patentee would obtain its expected value of $600,000 a year from the patent. Litigation costs and market uncertainties would certainly complicate the calculus, but they would not change the basic principle.

80 Of course, the settlement would not resolve questions about the patent's validity or coverage, whereas the court's judgment would, making the settlement less valuable to society.

81 See Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended in scattered sections of 15, 21, 28, and 35 U.S.C.). Tom Cotter has an excellent discussion of the details of Hatch-Waxman. See Thomas F. Cotter, Refining the "Presumptive Illegality" Approach to Settlements of Patent Disputes Involving Reverse Payments: A Commentary on Hovenkamp, Janis & Lemley, 87 Minn. L. Rev. 1789 (2003); see also Marcy Lobanoff, Comment, Anti-Competitive Agreements Cloaked as "Settlements" Thwart the Purposes of the Hatch-Waxman Act, 50 Emory L.J. 1331, 1332-1337 (2001).

82 See §§ 101-105, 98 Stat. at 1585-1603.

83 See 21 U.S.C. § 355(j)(5).

84 See *id.* § 355(b)(2)(a).

85 See *id.* § 355(j)(B)(iii).

86 See *id.* § 355(j)(B)(iv).

87 NDA applicants must file

the patent number and expiration date of any patent which claims the drug for which the applicant submitted the application or which claims the method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.

Id. § 355(b)(1). The FDA publishes this information in the "Orange Book." See *id.* § 355(j)(7)(A)(iii).

88 See, e.g., *Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323, 1328-1333 (Fed. Cir. 2001). In *Mylan*, a generic drug applicant sought to delist a patent from the Orange Book. *Id.* at 1325. The court denied the request, however, finding no such cause of action exists "outside a properly filed patent case." *Id.* at 1331-1333. For further discussion, see § 15.3c.

88.1 That section provides:

(ii) Counterclaim to infringement action

(I) In general

If an owner of the patent or the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order

requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) of this section on the ground that the patent does not claim either-

(aa) the drug for which the application was approved; or

(bb) an approved method of using the drug.

88.2 132 S. Ct. 1670 (2012).

88.3 601 F.3d 1359, 1368 (Fed. Cir. 2010).

88.4 132 S. Ct. at 1678.

89 See 21 U.S.C. § 355(j)(5)(B)(iii).

90 *Id.* § 355(j)(2)(A)(iv).

91 *Id.* § 355(j)(2)(A)(vii).

92 *Id.* § 355(j)(2)(A)(vii)(IV).

93 *Id.* § 355(j)(2)(B)(i)-(ii); see also 21 C.F.R. §§ 314.50(i), 314.94(a)(12) (2002) (describing requirements for patent certifications by ANDA filers).

94 21 U.S.C. § 355(j)(5)(B)(iii). The filing of an ANDA "for a drug claimed in a patent or the use of which is claimed in a patent" is a technical act of infringement under the patent statute. 35 U.S.C. § 271(e)(2)(A).

95 21 U.S.C. § 355(j)(5)(B)(iii).

96 *Id.*

97 *Id.* § 355(j)(5)(B)(iii)(I).

98 The potential for multiple stays arises because multiple different patents might cover various aspects of a single commercial drug product. The pioneer might list a first patent, subsequently sue an ANDA filer, and trigger a 30-month stay of the ANDA. If the pioneer then lists new patent information, the cycle may be started again: The ANDA filer would be compelled to make another certification, the pioneer could sue, and the FDA would initiate another 30-month stay.

99 21 U.S.C. § 355(j)(5)(C)(2).

100 Applications for FDA Approval to Market a New Drug, 68 Fed. Reg. 36,676-77, 21 C.F.R. pt. 314 (June 18, 2003).

101 See Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act, Pub. L. No. 98-417, § 101, 98 Stat. 1585, 1589 (1984) (codified as amended at 21 U.S.C. § 355(j)(5)(B)(iv)).

102 21 U.S.C. § 355(j)(5)(B)(iv). More precisely, this is the date on which the Secretary of Health and Human Services receives notice of the first commercial marketing of the generic drug under the first generic's ANDA. *Id.*

103 *Id.* Before 2000, the FDA regulations provided that a court decision triggered the 180-day exclusivity period only if the decision was a "final judgment from which no appeal can be or has been taken." 21 C.F.R. § 314.107(e)(1) (1999). Congress changed the law in 2003 so that the decision of a district court is sufficient to trigger the 180-day period.

104 21 C.F.R. § 314.107(c)(1).

105 140 F.3d 1060, 1066-1074 (D.C. Cir. 1998). See also *Granutec, Inc. v. Shalala*, 46 U.S.P.Q.2d (BNA) 1398, 1401 (4th Cir. 1998).

106 Guidance for Industry on 180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act; Availability, 63 Fed. Reg. 37,890, 37,890-91 (July 13, 1998). Proposed regulations implementing this approach are still pending. See 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 64 Fed. Reg. 42,873, 42,874 (Aug. 6, 1999).

106.1 C. Scott Hemphill & Mark A. Lemley, Earning Exclusivity: Generic Incentives and the Hatch-Waxman Act, 77 Antitrust L.J. 947 (2011) (reporting results of an empirical study on the basis of 180-day generic exclusivity awards).

107 Other agreements are even more clearly anticompetitive. For example, an agreement by a patentee and a potential generic entrant that the patentee will pay the generic to continue the lawsuit—and thus the automatic stay of any generic entry—without ever prosecuting it to a conclusion is clearly anticompetitive and lacks even the redeeming virtue of ending an expensive litigation. Such an agreement can be condemned as illegal per se. *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908 (6th Cir. 2003).

108 21 U.S.C. § 355(j)(5)(D)(i)(I).

108.1 For discussion, and a proposal to condition 180-day generic exclusivity on successful litigation by the generic, see C. Scott Hemphill & Mark A. Lemley, Earning Exclusivity: Generic Incentives and the Hatch-Waxman Act, 77 Antitrust L.J. 947 (2011).

109 In 2007 Bristol-Myers pled guilty and paid a criminal fine for failing to report an agreement that involved a reverse payment settlement of a pharmaceutical patent infringement suit and an agreement by one firm to stay out of the market in exchange for a large payment. The conviction was for violation of the federal False Statements Act, 18 U.S.C. § 1001. The guilty plea is reported at < www.usdoj.gov/atr/public/press_releases/2007/223634.htm >.

110 Federal Trade Commn. Generic Drug Entry Prior to Patent Expiration: An FTC Study 26 (2002), http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.

111 *Id. at 25*, http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.

112 *Id.* at 31-32, http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf. Although the sheer amount of the payment alone may seem sufficient to raise concerns about potential anticompetitive behavior, additional information would seem relevant as well—for example, the length of time over which the payout is being made (typically measured by the time between the agreement and patent expiration) and the value of the brand name product (measured, for example, in terms of the pioneer's net sales of the product annually). The FTC study includes such information for each of the nine agreements. *Id.*, http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.

113 http://www.ftc.gov/opa/2005/01/drugsettlement.htm.

114 See § 7.4e2.

114.1 http://www.ftc.gov/os/2011/10/1110mmaagree.pdf. Even in 2011, equally many cases settled without any delay or exclusion payment (28), and another 100 settled with delayed entry but without a payment.

115 Raymond Ku, Antitrust Immunity, the First Amendment and Settlements: Defining the Boundaries of the Right to Petition, 33 Ind. L. Rev. 385, 388-89 (2000).

116 See *Andrx Pharms., Inc. v. Biovail Corp.*, 256 F.3d 799 (D.C. Cir. 2001) (settlements not immune under *Noerr*); *In re Cardizem CD Antitrust Litigation*, 105 F. Supp. 2d 618 (E.D. Mich. 2000) (*Noerr* immunity did not shield agreements incidental to patent litigation), aff'd, 332 F.3d 896 (6th Cir. 2003); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188 (E.D.N.Y. 2003) (private settlement was not subject to *Noerr* immunity merely because it was submitted to a court for approval; the court seemed to confuse *Noerr* and state action immunity). *Cf. Andrx Pharms. v. Elan Corp.*, 421 F.3d 1227, 1235-36 (11th Cir. 2005) (applying *Noerr* to immunize Elan's patent infringement lawsuits but not its settlement of those suits). By contrast, the court in *In re Tamoxifen Citrate Antitrust Litig.*, 277 F. Supp. 2d 121 (E.D.N.Y. 2003) held that a petition by a generic manufacturer to the FDA to change a paragraph (iv) certification after a patent settlement triggered *Noerr* immunity. The court declined to decide whether the settlement agreement itself would be entitled to *Noerr* immunity. *Id.* at 135 n.11.

117 *Palmer v. BRG of Georgia*, 498 U.S. 46 (1990).

118 332 F.3d 896 (6th Cir. 2003).

119 *Id.* at 907-908.

120 *Id.* at 699, citing *Palmer v. BRG of Georgia*, 498 U.S. 46, 49-50 (1990), which applied the per se rule to condemn a horizontal territorial division agreement covering the entire United States even though one of the firms had never operated outside the state of Georgia. On this point, see 11 Antitrust Law ¶¶1901b; 1902a (2d ed. 2005).

121 105 F. Supp. 2d at 703.

121.1 This fact was also significant in the denial of defendant's motion to dismiss in *King Drug Co. v. Cephalon, Inc.*, 702 F. Supp. 2d 514 (E.D. Pa. 2010). There, the plaintiffs alleged that the settlement agreement included side agreements that the first generic filer agreed not to give up its 180-day exclusivity, an agreement that the court found to be beyond the scope of the patent.

121.2 That fact pattern was also driving the other case to have applied per se illegality (or at least presumptive illegality), the D.C. Circuit's decision in *Andrx Pharms., Inc. v. Biovail Corp.*, 256 F.3d 799 (D.C. Cir. 2001).

122 No. 9297 (F.T.C. Dec. 18, 2003), rev'd, *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005). We discuss the Eleventh Circuit opinion below.

123 Id.

124 *Id.* The Eleventh Circuit reversed the FTC's opinion. We retain discussion of it here, however, because subsequent FTC cases may be appealed to courts other than the Eleventh Circuit. For an endorsement of the FTC's approach, and implicit criticism of the Eleventh Circuit's, see Thomas F. Cotter, Antitrust Implications of Patent Settlements Involving Reverse Payments: Defending a Rebuttable Presumption of Illegality in Light of Some Recent Scholarship, 71 Antitrust L.J. 1069 (2004).

125 In re Cardizem CD Antitrust Litig., 332 F.3d 896, 908 (6th Cir. 2003).

126 See, e.g., Crane, *supra*, at 779-796; Willig & Bigelow, *supra*.

127 344 F.3d 1294 (11th Cir. 2003).

128 *Abbott Labs v. Geneva Pharms., Inc.*, 182 F.3d 1315 (Fed. Cir. 1999).

129 That doubt was justified; the patent was ultimately held invalid.

130 *Valley Drug*, 344 F.3d at 1310.

131 *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279, 1306 (S.D. Fla. 2005) (citing Treatise).

131.1 *King Drug Co. v. Cephalon, Inc.*, 702 F. Supp. 2d 514 (E.D. Pa. 2010).

132 *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 363 F. Supp. 2d 514 (E.D.N.Y. 2005), aff'd on other grounds, 544 F.3d 1323 (Fed. Cir. 2008).

133 Indeed, the plaintiffs presented evidence that $398 million was more than the generic would have made even if it had won the case.

134 402 F.3d 1056 (11th Cir. 2005).

135 *Id.* at 1065.

136 *Id.* at 1066.

137 *Id.* at 1068.

137.1 And indeed, district courts in the Eleventh Circuit have shown more deference to exclusion payments since *Schering-Plough*. While the district court on remand in *Valley Drug* inquired into who would have won the underlying patent suit, the district court in *In re AndroGel Antitrust Litig.*, 687 F. Supp. 2d 1371 (N.D. Ga. 2010) refused even to consider the likelihood that the patentee would have won the suit, and treated the fact of an exclusion payment as wholly irrelevant to an antitrust analysis.

138 Cf. *In re K-Dur Antitrust Litig.*, __ F.3d __, 2012 WL 2877662 (3d Cir. July 16, 2012) (rejecting application of the "scope of the patent" test in a case involving infringement, not validity; noting that the presumption of validity cannot apply to an infringement case).

139 402 F.3d at 1066.

140 The question of separate business deals as "payments" for exclusion also arose in *FTC v. Warner Chilcott Holdings Co.*, 2006 WL 3302862 (D.D.C. Oct. 23, 2006), where the FTC and the defendant entered into a stipulated preliminary injunction forbidding Warner Chilcott from settling patent cases by providing the defendant with anything of value, including a separate supply agreement.

141 C. Scott Hemphill, An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition, 109 Colum. L. Rev. 629 (2009) (discussing the ways in which introduced complexity interferes with antitrust enforcement against settlement disputes).

142 466 F.3d 187 (2d Cir. 2006).

143 *Id*. at 202.

144 *Id*. at 387.

145 *Id*. at 392.

146 *Id*.

147 See § 11.3c (discussing the difficulty antitrust plaintiffs have in showing sham litigation to overcome *Noerr* immunity).

148 429 F.3d at 396.

149 See § 15.3a1(C), (D) (discussing such options).

150 *Id*.

151 *Id*. at 408 (Pooler, J., dissenting).

152 *Id*. at 226.

153 544 F.3d 1323 (Fed. Cir. 2008).

154 The case arose from a district court in the Second Circuit. The Federal Circuit normally applies regional circuit antitrust law. In this case, it cited the law of the Second Circuit but did not specify whether it was applying *Tamoxifen* as binding law or drawing its own legal conclusions. Resolution of this question will be important if future cases are appealed to the Federal Circuit from circuits that, unlike the Second Circuit, apply per se or full rule of reason analyses. For discussion of the issue, see § 5.3a.

155 *Id.* at 1332.

156 *Id.* at 1335.

157 *Id.* at 1336. Curiously, the Federal Circuit cited *Valley Drug* and the FTC's approach in *Schering* in support of this conclusion, when in fact both the Eleventh Circuit and the FTC took precisely the opposite approach.

158 *Id.* at 1337.

158.1 *In re K-Dur Antitrust Litig.*, __ F.3d __, 2012 WL 2877662 (3d Cir. July 16, 2012).

158.2 *Id*.

158.3 *Id*. at *12.

158.4 *Id*. (citing *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1534 (Fed. Cir. 1983)).

158.5 329 U.S. 394 (1947).

158.6 *Id*. at 400; see also *Sola Elec. Co. v. Jefferson Elec. Co.*, 317 U.S. 173, 177 (1942).

158.7 *K-Dur*, 2012 WL 2877662, at *15.

158.8 *Id*. at *16.

158.9 *Id*.

158.10 *FTC v. Watson Pharms., Inc.*, 677 F.3d 1298 (11th Cir. 2012).

158.11 *In re Cipro Cases I & II*, 134 Cal. Rptr. 3d 165 (Ct. App. 2011), review granted, 269 P.3d 653 (Cal. 2012). Applying the Cartwright Act, the court of appeal followed *Tamoxifen* and held that a settlement of a patent suit "within the scope of the patent" was immune from scrutiny unless the underlying lawsuit was a sham. Notably, the grant of review by the California Supreme Court supersedes the court of appeal opinion and makes the case uncitable in California courts.

158.12 The Third Circuit recognized *Watson*'s departure in *In re K-Dur* (after *Watson*, Eleventh Circuit standard is "identical to the scope of the patent test applied by the Second Circuit" in *Tamoxifen*).

159 *FTC v. Cephalon, Inc.*, Complaint for Injunctive Relief, available at http://www.ftc.gov/os/caselist/0610182/080213complaint.pdf. For a discussion of the facts, see Michael A. Carrier, Provigil: A Case Study of Anticompetitive Behavior, 3 Hastings Sci. & Tech. L.J. 441 (2011).

160 *In re Lorazepam & Clorazepate Antitrust Litig.*, 531 F. Supp. 2d 82 (D.D.C. 2008).

160.1 604 F.3d 98 (2d Cir. 2010).

160.2 *Id*. at 108-110.

160.3 *Arkansas Carpenters Health and Welfare Fund v. Bayer AG*, 625 F.3d 779 (2d Cir. 2010).

161 See Cotter, *supra* note 81 1789, 1798 n.43 (2003). For a discussion of rare instances of such payments, see Robert J. Hoerner, Antitrust Pitfalls in Patent Litigation Settlement Agreements, 8 Fed. Cir. B.J. 113, 121-123 (1998). In cross-licenses, of course, net payments could go from one party to another depending on the relative value of the patents each licensor holds. But where only one party owns a patent, it is virtually unheard of outside of pharmaceuticals for that party to pay an accused infringer to settle the lawsuit. *Cf.* M. Howard Morse, Settlement of Intellectual Property Disputes in the Pharmaceutical and Medical Device Industries: Antitrust Rules, 10 Geo. Mason L. Rev. 359, 362 (2002) (noting that pharmaceutical settlements may sometimes include "side deals" justifying such a payment).

162 Hatch-Waxman also changes the general economic analysis of the costs and benefits of litigation. Because the law provides for an automatic stay of entry by generic manufacturers once the pharmaceutical patentee files suit, patentees do not lose profits and defendants do not gain profits unless and until the patent is determined to be invalid or noninfringed. Compare Cotter, *supra* note 124, at 1800-1801, with *id.* at 1802-1805 (discussing how this affects the settlement calculus).

163 363 F. Supp. 2d 514 (E.D.N.Y. 2005), aff'd, 544 F.3d 1323 (Fed. Cir. 2008).

164 The Federal Circuit responded to this concern by reasoning that the more likely a patent is to be invalid, the more generic companies will seek to challenge it. But because of Hatch-Waxman, a pharmaceutical company can buy months or years of exclusion by settling with a single generic firm even if other generics will eventually enter the market.

165 For example, a pioneer's willingness to pay 10 percent of its profits as an exclusion payment to a generic rival suggests that the pioneer's profit-maximizing price is at least 10 percent above its costs. That market power may well have been legally conferred by an IP right, but the validity of that right is the very subject at issue in a settlement case. It is also no answer to say that judges lack significant experience with exclusion payments, and as a result these should be governed by the full role of reason. See Morse, *supra* note 87, at 361-362 (arguing for a rule of reason approach in most cases). Consider, for example, *In re Schering-Plough Corp.*, in which the ALJ applied the rule of reason because judges lacked experience with Hatch-Waxman-style exclusion payments and dismissed the complaint. See No. 9297, slip op. at 98 (June 27, 2002) (initial decision), available at http://www.ftc.gov/os/2002/07/scheringinitialdecisionp2.pdf. The "judicial experience" argument runs to classes of restraints, not to particular products. An exclusion payment is in fact a type of naked horizontal market division agreement, which have been unlawful for a long time. For example, if a group of skateboard manufacturers should fix prices, one would not say that judicial experience with price fixing in skateboards is very limited, so the rule of reason should be applied.

166 See, e.g., Carl Shapiro, Antitrust Limits to Patent Settlements, 34 Rand J. Econ. 391 (2003); Cotter, note 124, at 1806 tbl.1.

167 Cotter, note 81, at 1805-1807.

168 *Id.* at 1808-1811.

169 See *id.* at 1806.

170 *Id.* at 1808-1809. Crane acknowledges this, though curiously he considers it a virtue rather than a problem of exclusion payments. Daniel A. Crane, Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications, 54 Fla. L. Rev. 747, 774 (2002) ("The 'directional flow' of the settlement payment, therefore, will be affected by the probability of the plaintiff's lawsuit succeeding.").

171 See Cotter, note 124 at 1806 tbl.1.

172 See *id.*

173 Cf. George L. Priest, Cartels and Patent License Arrangements, 20 J.L. & Econ. 309, 327 (1977) (arguing that rational patentees won't reduce the royalty below zero unless they are cartelizing an industry). It is true, of course, that some patents that go to trial will be held valid and infringed, and therefore the patentee will keep its monopoly. But the anticompetitive harm comes from the fact that the settlement forecloses the incremental chance that the market would be competitive. Significantly, it is this very foreclosure that makes exclusion payments greater than the cost of litigation rational.

174 See Roger D. Blair & Thomas F. Cotter, Are Settlements of Patent Disputes Illegal Per Se?, 47 Antitrust Bull. 491, 534-538 (2002); Michael A. Carrier, Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality, 108 Mich. L. Rev. 37 (2009); cf. Crane, note 169, at 779-796 (arguing that antitrust should permit such settlements when the ex ante success of the patent infringement suit is high and prohibit them when the ex ante success is low). At the same time, however, other things being equal, the higher the objectively measured ex ante success of the infringement suit, the less the expected size of the payment to the infringement defendant. *Id.* at 780-782. For example, if the patentee was 100 percent sure of victory in the patent infringement suit, a settlement payment would not exceed the amount of expected litigation costs. See *id.* Thus, we think it reasonable to require both proof of likely success on the merits and, because it is evidentiary of likely outcomes, proof that the payment to the accused infringer did not exceed the patentee's expected litigation costs. Although Cotter is critical of our proposed limit on the size of exclusion payments, he is in general agreement with our position that they should be presumptively illegal. See Cotter, note 87, at 1797-1798. Unlike us, he would permit a more open-ended inquiry into how large a payment should be permitted. See *id.*

The definition of litigation costs will also matter in practice. We think they should be limited to a good faith estimate of the out-of-pocket costs and attorney's fees the patentee could expect to pay between the time of the settlement and the time the case was concluded. Although Robert Willig and John Bigelow have suggested that the value of uncertainty could be included in "litigation costs," Robert D. Willig & John P. Bigelow, Antitrust Policy Towards Agreements That Settle Patent Litigation, 41 J. Econ. Lit. (2003), we think this impermissibly brings in the value of certain exclusion based on a doubtful patent under the rubric of litigation expenses.

174.1 Of course, if the parties can prove that there is no payment in exchange for exclusion or entry delay, the presumption of illegality would not apply. See *In re K-Dur Antitrust Litig.*, __ F.3d __, 2012 WL 2877662 (3d Cir. July 16, 2012).

175 We discuss settlements that authorize generic entry *in* § 15.3a2.

176 See Cotter, *supra*, at 1809-1810 nn. 78-79. He concedes, however, that the analogy is imperfect. *Id.* at 28 n.79.

177 Shapiro, *supra*, note 166.

178 See John R. Allison & Mark A. Lemley, Empirical Evidence on the Validity of Litigated Patents, 26 AIPLA Q.J. 185, 205-207 (1998) (finding that 46 percent of patents litigated to judgment are held invalid); Kimberly A. Moore, Judges, Juries and Patent Cases—An Empirical Peek Inside the Black Box, 99 Mich. L. Rev. 365, 390 (2000) (finding that 33 percent of patents litigated to *trial* are held invalid).

178.1 By contrast, if the patent is actually determined to be valid and infringed, the exclusion of generic competition results from that conclusion, not from a settlement. *In re Plavix Indirect Purchaser Antitrust Litig.*, 2011 WL 335034 (S.D. Ohio Jan. 31, 2011) ("To the extent a patent is valid – and the Federal Circuit has affirmed the validity of the '265 patent and the USPTO has repeatedly declined to re-review it—a patent lawfully excludes competition.…Plaintiffs' alleged injury—paying 'artificially inflated prices for Plavix'—derives from the lack of access to a generic substitute caused by the court-ordered injunctions barring sales of a generic…").

179 For endorsement of such an approach as procompetitive, see Willig & Bigelow, *supra* note 173.

180 Actually, the determination of the length of the delay is a bit more complicated than suggested in the text. First, the relevant period to be divided should begin when the trial would end, or when the 30-month stay would end, whichever is earlier; the generic couldn't enter before that date anyway. Second, because of the time value of money, the first five years of a ten-year period will provide more than 50 percent of the expected return over that period. The real calculation of the efficient delay will need to take into account the discount rate.

181 O'Rourke and Brodley also endorse delayed entry as an alternative to exclusion payments. See Joseph F. Brodley & Maureen A. O'Rourke, Patent Settlement Agreements, Antitrust, Summer 2002, at 53, 55; Maureen A. O'Rourke & Joseph Brodley, An Incentives Approach to Patent Settlements, 87 Minn. L. Rev. 1767, 1786-1787 (2003).

182 For a more skeptical view of settlements that delay entry, even without a payment, see C. Scott Hemphill, Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem, 81 N.Y.U. L. Rev. 1553 (2006).

182.1 For an argument that generics who settle paragraph (IV) challenges should not be allowed to maintain 180-day generic exclusivity, see C. Scott Hemphill & Mark A. Lemley, Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act, 77 Antitrust L.J. 947 (2011).

183 Courts do this already in the context of patent pools and cross-license agreements. See § 34.4a1. O'Rourke and Brodley worry that tests of this sort are indeterminate, O'Rourke & Brodley, *supra* note 21, at 1781-1782, but we don't see a good alternative.

184 An administrative board of the PTO, the Board of Patent Appeals and Interferences, hears patent interference proceedings. The Board's decisions are subject to appeal to the Court of Appeals for the Federal Circuit.

185 See 37 C.F.R. §§ 1.601-1.690 for the relevant regulations governing interference practice.

186 For a classic definition of "conception," see *Mergenthaler v. Scudder*, 11 App. D.C. 264 (1897) ; *Coleman v. Dines*, 754 F.2d 353 (Fed. Cir. 1985). For an explanation of reduction to practice concepts, see, e.g., *Scott v. Finney*, 34 F.3d 1058 (Fed. Cir. 1994).

187 See 35 U.S.C. § 102(g) for the rules on priority of invention. Section 102(g) calls for evidence of diligence when a party is the first to conceive an invention but the last to reduce the invention to practice.

188 35 U.S.C. § 102(g).

189 427 F.3d 958 (Fed. Cir. 2005). To the extent it is relevant, M.L. represented Genentech in this case.

190 35 U.S.C. § 135(c).

191 374 U.S. 174 (1963).

192 *Id*. at 199 (White, J., concurring).

193 427 F.3d at 965 - 66.

194 *Id*. at 966.

195 [Reserved].

196 On the antitrust standing of such nascent firms, see 2A Antitrust Law ¶349.

197 *Andrx Pharmaceuticals, Inc. v. Biovail Corp.*, 256 F.3d 799 (D.C. Cir. 2001). Cf. *Bristol-Meyers Squibb Co. v. Copley Pharmaceutical Co.*, 144 F. Supp. 2d 21 (D. Mass. 2001) (generic manufacturer who had not yet obtained preliminary regulatory approval to enter market lacked standing to claim that owner of branded pharmaceutical had filed baseless patent infringement suit; in addition, the generic manufacturer was the second, not the first, generic to file its intent to enter the market, and under the Hatch-Waxman Act first filer would have received a 180-day period of exclusivity in any event); *Eon Labs Manufacturing v. Watson Pharmaceuticals* , 164 F. Supp. 2d 350 (S.D.N.Y. 2001) (similar). Contrast *XeChem, Inc. v. Bristol-Myers Squibb* , 372 F.3d 899 (7th Cir. 2004) (refusing to dismiss complaint).

Cf.Bristol-Meyers Squibb Co. v. Ben Venue Laboratories , 90 F. Supp. 2d 540 (D.N.J. 2000). The patentee of the branded pharmaceutical brought an infringement suit against generic manufacturers who had filed an ANDA. The generics then counterclaimed, alleging that the infringement suit was a *Walker Process* antitrust violation. On such violations, see §11.2. The branded manufacturer then asserted that the counterclaimants lacked standing because their generics had not received even tentative FDA approval. The counter-claimants responded that the costs of defending a wrongful infringement suit were antitrust damages, as well as losses related to inability to market generic drug. On this measure of damages see 3 Antitrust Law ¶706f (2d ed. 2002). The court found standing:

> Bristol's argument ignores the reality of Hatch-Waxman. There is no dispute that by suing the generic defendants under the Hatch-Waxman Act, Bristol provoked the automatic moratorium of FDA approval of the generics' ANDAs. For Bristol to insist that its generic competitors have no standing because they are not in the market, when Bristol itself foreclosed their access to it, is meritless.…
>
> In a classic patent infringement case, a patentee may sue an alleged infringer only when the defendant "makes, uses, offers to sell, or sells" a patented invention—in other words, upon its actual entry into the market. See 35 U.S.C. §271(a). Concomitantly, doctrines of antitrust standing have evolved to require that a competitor be prepared to enter the market before bringing antitrust claims. … In contrast, under the Hatch-Waxman Act, a patentee may sue a generic drug company when it submits an ANDA. See 35 U.S.C. §271(e). The purpose of this is to allow drug patentholders to quickly resolve competing claims in court, before their competitors make inroads into the market. See *Eli Lilly & Co. v. Medtronic* , 496 U.S. 661, 675, 677, 110 S. Ct. 2683, 110 L. Ed. 2d 605 (1990) (finding that the function of §§271(e)(2) and 271(e)(4) is "to define a new (and somewhat artificial) act of infringement" in order to "enable the judicial adjudication upon which the ANDA and paper NDA schemes depend.").
>
> Were the court to accept Bristol's position, antitrust standing under the Hatch-Waxman Act would be wholly contingent on the vagaries of the timing of agency action. If the FDA acted immediately to grant conditional approval to an ANDA, the generic applicant would have standing to bring antitrust claims. But if, as here, the patentee beat the applicant to the punch by filing a motion to dismiss before FDA approval, the generic maker would be denied antitrust standing. Such an anomalous and arbitrary result was not intended by the statute.

90 F. Supp. 2d at 540.

198 256 F.3d at 807.

199 *Id.*

200 *Id.*

114 See § 7.4e2.

114.1 http://www.ftc.gov/os/2011/10/1110mmaagree.pdf. Even in 2011, equally many cases settled without any delay or exclusion payment (28), and another 100 settled with delayed entry but without a payment.

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116 See *Andrx Pharms., Inc. v. Biovail Corp*., 256 F.3d 799 (D.C. Cir. 2001) (settlements not immune under *Noerr*); *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 618 (E.D. Mich. 2000) (*Noerr* immunity did not shield agreements incidental to patent litigation), aff'd, 332 F.3d 896 (6th Cir. 2003); *In re Ciprofloxacin Hydrochloride Antitrust Litig*., 261 F. Supp. 2d 188 (E.D.N.Y. 2003) (private settlement was not subject to *Noerr* immunity merely because it was submitted to a court for approval; the court seemed to confuse *Noerr* and state action immunity). *Cf. Andrx Pharms. v. Elan Corp*., 421 F.3d 1227, 1235-36 (11th Cir. 2005) (applying *Noerr* to immunize Elan's patent infringement lawsuits but not its settlement of those suits). By contrast, the court in *In re Tamoxifen Citrate Antitrust Litig*., 277 F. Supp. 2d 121 (E.D.N.Y. 2003) held that a petition by a generic manufacturer to the FDA to change a paragraph (iv) certification after a patent settlement triggered *Noerr* immunity. The court declined to decide whether the settlement agreement itself would be entitled to *Noerr* immunity. *Id.* at 135 n.11.

117 32 F.3d 896 (6th Cir. 2003).

118 No. 9297 (F.T.C. Dec. 18, 2003), rev'd, *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005). We discuss the Eleventh Circuit opinion below.

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120 344 F.3d 1294 (11th Cir. 2003).

121 *Abbott Labs v. Geneva Pharms., Inc.*, 182 F.3d 1315 (Fed. Cir. 1999).

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123 *Id.* at 1065.

124 *Id.* at 1066.

125 *Id.* at 1068.

126 And indeed, district courts in the Eleventh Circuit have shown more deference to exclusion payments since *Schering-Plough*. While the district court on remand in *Valley Drug* inquired into who would have won the underlying patent suit, the district court in *In re AndroGel Antitrust Litig.*, 687 F. Supp. 2d 1371 (N.D. Ga. 2010) refused even to consider the likelihood that the patentee would have won the suit, and treated the fact of an exclusion payment as wholly irrelevant to an antitrust analysis.

127 466 F.3d 187 (2d Cir. 2006).

128 *Id*.

129 See § 11.3c (discussing the difficulty antitrust plaintiffs have in showing sham litigation to overcome *Noerr* immunity).

130 544 F.3d 1323 (Fed. Cir. 2008).

131 The case arose from a district court in the Second Circuit. The Federal Circuit normally applies regional circuit antitrust law. In this case, it cited the law of the Second Circuit but did not specify whether it was applying *Tamoxifen* as binding law or drawing its own legal conclusions. For discussion of the issue, see § 5.3a.

132 *Id.* at 1332.

133 *Id.* at 1335.

134 *Id*.

135 *Id*. at *16.

136 *Id*.

137 570 U.S. ____, 133 S. Ct. 2223 (2013).

138 *Id*. at 2230.

139 *FTC v. Watson Pharms., Inc.*, 677 F.3d 1298, 1312 (11th Cir. 2012).

140 *Actavis*, 570 U.S. at __, 133 S. Ct. at 2227.

141 *Id*. at 2230.

142 *Id*. at 2231 (emphasis in original).

143 *Id*.

144 *Id*. at 2231-32 (emphasis in original).

145 *Id*. at 2233. Chief Justice Roberts, dissenting, challenged the Court's interpretation of those precedents, arguing that none of them involved the situation presented here—the settlement of a suit over a single patent with market division, as opposed to a patent pool or price-fixing agreement. *Id*. at 2239-43 (Roberts, C.J., dissenting).

146 *Id*. at 2234.

147 *Id*. at 2234-35.

148 *Id*. at 2235.

149 *Id*. at 2236.

150 *Id*. at 2237.

151 *Id*. at 2236.

152 *Id*. at 2237.

153 *Id*. at 2238.

154 *Actavis,* 133 S. Ct. at 2236 (making this point). For example, a pioneer's willingness to pay 10 percent of its profits as an exclusion payment to a generic rival suggests that the pioneer's profit-maximizing price is at least 10 percent above its costs. That market power may well have been legally conferred by an IP right, but the validity of that right is the very subject at issue in a settlement case. It is also no answer to say that judges lack significant experience with exclusion payments, and as a result these should be governed by the full role of reason. See Morse, *supra* note 87, at 361-362 (arguing for a rule of reason approach in most cases). Consider, for example, *In re Schering-Plough Corp.*, in which the ALJ applied the rule of reason because judges lacked experience with Hatch-Waxman-style exclusion payments and dismissed the complaint. See No. 9297, slip op. at 98 (June 27, 2002) (initial decision), available at http://www.ftc.gov/os/2002/07/scheringinitialdecisionp2.pdf. The "judicial experience" argument runs to classes of restraints, not to particular products. An exclusion payment is in fact a type of naked horizontal market division agreement, which have been unlawful for a long time. For example, if a group of skateboard manufacturers should fix prices, one would not say that judicial experience with price fixing in skateboards is very limited, so the rule of reason should be applied.

155 See, e.g., Carl Shapiro, Antitrust Limits to Patent Settlements, 34 Rand J. Econ. 391 (2003); Cotter, supra note 124, at 1806 tbl.1.

156 Cf. George L. Priest, Cartels and Patent License Arrangements, 20 J.L. & Econ. 309, 327 (1977) (arguing that rational patentees won't reduce the royalty below zero unless they are cartelizing an industry). It is true, of course, that some patents that go to trial will be held valid and infringed, and therefore the patentee will keep its monopoly. But the anticompetitive harm comes from the fact that the settlement forecloses the incremental chance that the market would be competitive. Significantly, it is this very foreclosure that makes exclusion payments greater than the cost of litigation rational. The regulatory nature of Hatch-Waxman makes such a payment particularly likely, because the FDA's restrictions on entry mean that paying off a single competitor may prevent all competition, at least for a time. Indeed, the Supreme Court observed that "where only one party owns a patent, it is virtually unheard of outside of pharmaceuticals for that party to pay an accused infringer to settle the lawsuit." *Actavis*, 133 S. Ct. at 2233 (quoting Treatise).

157 *Thomas F. Cotter, FTC v. Actavis, Inc.*: When is the Rule of Reason Not the Rule of Reason?, 15 Minn. J. L., Sci. & Tech. (forthcoming 2013).

158 *Actavis*, 133 S.Ct. at 2235.

159 *Id.* at 2236-37.

160 *Id.* at 2236.

161 *Id*. at 2236-37.

162 "The reverse payment, for example, may amount to no more than a rough approximation of the litigation expenses saved through the settlement. That payment may reflect compensation for other services that the generic has promised to perform—such as distributing the patented item or helping to develop a market for that item. There may be other justifications. Where a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement." *Id*. See also *id*. at 2237 ("the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification.").

163 *Id*. at 2237.

164 *Id*. at 2236 ("The reverse payment, for example, may amount to no more than a rough approximation of the litigation expenses saved through the settlement."); *id*. ("Where a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern").

165 *Id*.

166 *Actavis*, 133 S. Ct. at 2233 (quoting. *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969)).

167 For discussion of those anticompetitive effects, see Herbert Hovenkamp, Antitrust Scrutiny of Anticompetitive Patent Settlements: the Supreme Court's Actavis Decision (working paper 2013).

168 *Valley Drug*, 344 F.3d 1294.

169 See Roger D. Blair & Thomas F. Cotter, Are Settlements of Patent Disputes Illegal Per Se?, 47 Antitrust Bull. 491, 534-538 (2002); Michael A. Carrier, Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality, 108 Mich. L. Rev. 37 (2009); cf. Crane, supra note 169, at 779-796 (arguing that antitrust should permit such settlements when the ex ante success of the patent infringement suit is high and prohibit them when the ex ante success is low).

170 *Actavis*, 133 S. Ct. at 2236; see also *id*. at 2237 ("Where a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern").

171 Robert D. Willig & John P. Bigelow, Antitrust Policy Towards Agreements That Settle Patent Litigation, 41 J. Econ. Lit. (2003).

172 *Actavis*, 133 S. Ct. at 2236 ("The owner of a particularly valuable patent might contend, of course, that even a small risk of invalidity justifies a large payment. But, be that as it may, the payment (if otherwise unexplained) likely seeks to prevent the risk of competition. And, as we have said, that consequence constitutes the relevant anticompetitive harm.").

173 Of course, if the parties can prove that there is no payment in exchange for exclusion or entry delay, *Actavis* would not apply. We discuss such cases in the next section.

174 The question of separate business deals as "payments" for exclusion also arose in *FTC v. Warner Chilcott Holdings Co.*, 2006 WL 3302862 (D.D.C. Oct. 23, 2006), where the FTC and the defendant entered into a stipulated preliminary injunction forbidding Warner Chilcott from settling patent cases by providing the defendant with anything of value, including a separate supply agreement.

175 C. Scott Hemphill, An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition, 109 Colum. L. Rev. 629 (2009) (discussing the ways in which introduced complexity interferes with antitrust enforcement against settlement disputes). Hemphill argues for a ban on "complex" settlements, but we don't see how that would work. The parties could always enter into separate side agreements. Courts must be willing to assess the legitimacy of side deals that purport to justify a payment.

176 By contrast, if the patent is actually determined to be valid and infringed, the subsequent exclusion of generic competition results from that conclusion, not from a settlement. *In re Plavix Indirect Purchaser Antitrust Litig.*, 2011 WL 335034 (S.D. Ohio Jan. 31, 2011) ("To the extent a patent is valid – and the Federal Circuit has affirmed the validity of the '265 patent and the USPTO has repeatedly declined to re-review it—a patent lawfully excludes competition.…Plaintiffs' alleged injury—paying 'artificially inflated prices for Plavix'—derives from the lack of access to a generic substitute caused by the court-ordered injunctions barring sales of a generic…").

177 For endorsement of such an approach as procompetitive, see Willig & Bigelow, *supra* note 156.

178 Actually, the determination of the length of the delay is a bit more complicated than suggested in the text. First, the relevant period to be divided should begin when the trial would end, or when the 30-month stay would end, whichever is earlier; the generic couldn't enter before that date anyway. Second, because of the time value of money, the first five years of a ten-year period will provide more than 50 percent of the expected return over that period. The real calculation of the efficient delay will need to take into account the discount rate.

179 O'Rourke and Brodley also endorse delayed entry as an alternative to exclusion payments. See Joseph F. Brodley & Maureen A. O'Rourke, Patent Settlement Agreements, Antitrust, Summer 2002, at 53, 55; Maureen A. O'Rourke & Joseph Brodley, An Incentives Approach to Patent Settlements, 87 Minn. L. Rev. 1767, 1786-1787 (2003).

180 See, e.g., *In re Lamictal Direct Purchaser Antitrust Litig.*, 2012 WL 6725580 (D.N.J. Dec. 6, 2012) (holding that a mere agreement to delay entry without a payment was not illegal; granting a motion to dismiss). For a more skeptical view of settlements that delay entry, even without a payment, see C. Scott Hemphill, Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem, 81 N.Y.U. L. Rev. 1553 (2006). Hemphill's argument is that the fact of 180-day generic exclusivity will incline settling generics to delay entry longer than would be ideal.

181 *Actavis*, 133 S. Ct. at 2237.

182 For an argument that generics who settle paragraph (IV) challenges should not be allowed to maintain 180-day generic exclusivity, see C. Scott Hemphill & Mark A. Lemley, Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act, 77 Antitrust L.J. 947 (2011).

182.1 *In re Skelaxing (Metaxalone) Antitrust Litig.*, 2013 WL 2181185 (E.D. Tenn. May 20, 2013).

183 Courts do this already in the context of patent pools and cross-license agreements. See § 34.4a1. O'Rourke and Brodley worry that tests of this sort are indeterminate, O'Rourke & Brodley, *supra* note 21, at 1781-1782, but we don't see a good alternative.

184 An administrative board of the PTO, the Board of Patent Appeals and Interferences, hears patent interference proceedings. The Board's decisions are subject to appeal to the Court of Appeals for the Federal Circuit.

185 See 37 C.F.R. §§ 1.601 - 1.690 for the relevant regulations governing interference practice.

186 For a classic definition of "conception," see *Mergenthaler v. Scudder*, 11 App. D.C. 264 (1897); *Coleman v. Dines*, 754 F.2d 353 (Fed. Cir. 1985). For an explanation of reduction to practice concepts, see, e.g., *Scott v. Finney*, 34 F.3d 1058 (Fed. Cir. 1994).

187 See 35 U.S.C. § 102(g) for the rules on priority of invention. Section 102(g) calls for evidence of diligence when a party is the first to conceive an invention but the last to reduce the invention to practice.

188 35 U.S.C. § 102(g).

189 427 F.3d 958 (Fed. Cir. 2005). To the extent it is relevant, M.L. represented Genentech in this case.

190 35 U.S.C. § 135(c).

191 374 U.S. 174 (1963).

192 *Id*. at 199 (White, J., concurring).

193 427 F.3d at 965 - 66.

194 *Id*. at 966.

195 [Reserved].

196 On the antitrust standing of such nascent firms, see 2A Antitrust Law ¶349.

197 *Andrx Pharmaceuticals, Inc. v. Biovail Corp*., 256 F.3d 799 (D.C. Cir. 2001). Cf. *Bristol-Meyers Squibb Co. v. Copley Pharmaceutical Co*., 144 F. Supp. 2d 21 (D. Mass. 2001) (generic manufacturer who had not yet obtained preliminary regulatory approval to enter market lacked standing to claim that owner of branded pharmaceutical had filed baseless patent infringement suit; in addition, the generic manufacturer was the second, not the first, generic to file its intent to enter the market, and under the Hatch-Waxman Act first filer would have received a 180-day period of exclusivity in any event); *Eon Labs Manufacturing v. Watson Pharmaceuticals*, 164 F. Supp. 2d 350 (S.D.N.Y. 2001) (similar). Contrast *XeChem, Inc. v. Bristol-Myers Squibb*, 372 F.3d 899 (7th Cir. 2004) (refusing to dismiss complaint).

Cf.Bristol-Meyers Squibb Co. v. Ben Venue Laboratories, 90 F. Supp. 2d 540 (D.N.J. 2000). The patentee of the branded pharmaceutical brought an infringement suit against generic manufacturers who had filed an ANDA. The generics then counterclaimed, alleging that the infringement suit was a *Walker Process* antitrust violation. On such violations, see § 11.2. The branded manufacturer then asserted that the counterclaimants lacked standing because their generics had not received even tentative FDA approval. The counter-claimants responded that the costs of defending a wrongful infringement suit were antitrust damages, as well as losses related to inability to market generic drug. On this measure of damages see 3 Antitrust Law ¶706f (2d ed. 2002). The court found standing:

> Bristol's argument ignores the reality of Hatch-Waxman. There is no dispute that by suing the generic defendants under the Hatch-Waxman Act, Bristol provoked the automatic moratorium of FDA approval of the generics' ANDAs. For Bristol to insist that its generic competitors have no standing because they are not in the market, when Bristol itself foreclosed their access to it, is meritless.…
>
> In a classic patent infringement case, a patentee may sue an alleged infringer only when the defendant "makes, uses, offers to sell, or sells" a patented invention—in other words, upon its actual entry into the market. See 35 U.S.C. § 271(a). Concomitantly, doctrines of antitrust standing have evolved to require that a competitor be prepared to enter the market before bringing antitrust claims. …In contrast, under the Hatch-Waxman Act, a patentee may sue a generic drug company when it submits an ANDA. See 35 U.S.C. § 271(e). The purpose of this is to allow drug patentholders to quickly resolve competing claims in court, before their competitors make inroads into the market. See *Eli Lilly & Co. v. Medtronic*, 496 U.S. 661, 675, 677, 110 S. Ct. 2683, 110 L. Ed. 2d 605 (1990) (finding that the function of §§ 271(e)(2) and 271(e)(4) is "to define a new (and somewhat artificial) act of infringement" in order to "enable the judicial adjudication upon which the ANDA and paper NDA schemes depend.").
>
> Were the court to accept Bristol's position, antitrust standing under the Hatch-Waxman Act would be wholly contingent on the vagaries of the timing of agency action. If the FDA acted immediately to grant conditional approval to an ANDA, the generic applicant would have standing to bring antitrust claims. But if, as here, the patentee beat the applicant to the punch by filing a motion to dismiss

before FDA approval, the generic maker would be denied antitrust standing. Such an anomalous and arbitrary result was not intended by the statute.

90 F. Supp. 2d at 540.

198 256 F.3d at 807.

199 *Id.*

200 *Id.*

201 *In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677 (2d Cir. 2009).

201.1 *Cf. Louisiana Wholesale Drug Co. v. Shire LLC*, 2013 WL 950833 (S.D.N.Y. Mar. 6, 2013) (patentee not liable for antitrust violation for granting licenses to authorized generics and then breaching those contracts by failing to supply the drug; partial entry by the generics resulted in lower prices than if the patentee had not authorized any generics at all). *Shire* is based heavily on the now-rejected Second Circuit "scope of the patent" test in *Tamoxifen*; it is not clear how the case would come out under the current legal standard. But had the patentee succeeded in enforcing its patents and then granted licenses, rather than settling with an authorized generic license, it would be hard to fault the patentee's conduct.

202 On the problem of authorized generics, or generic drugs introduced by the pioneer manufacturer at about the same time that a generic competitor emerges, see Federal Trade Commission, Statement before Special Committee on Aging, United States Senate (July 20, 2006) (noting problem that issuance of authorized generic can reduce incentive of independent generic firm to enter market); see also the settlement in *FTC v. Warner Chilcott Pharms.*, available at http://www.ftc.gov/os/caselist/0410034/0410034.shtm (barring respondent from issuing authorized generic while paying independent generic company to stay out of market). The FTC's conclusions are contained in a report issued in 2011, see http://www.ftc.gov/os/2011/08/2011genericdrugreport.pdf. Notably, the FTC declined in that report to recommend action against authorized generics.

203 *Cf. Teva Pharmaceutical Indus. v. Smithkline Beecham Corp.*, 2009 WL 1687457 (D.N.J. June 16, 2009) (finding that GSK did not violate its settlement agreement with Teva by pricing its branded drug to compete with Teva's generic; GSK was entitled under the contract to price its drug any way it wished).

204 454 F.3d 270 (4th Cir. 2006).

205 289 F. Supp. 2d 986 (N.D. Ill. 2003) (citing Treatise).

206 The court's entire discussion is dictum, since the court ruled that Asahi as a supplier lacked standing to challenge the agreement in any event.

207 *Asahi* at 993.

208 *Id.* at 994.

209 One court has held that a generic drug manufacturer lacks antitrust standing to challenge such an agreement, because it is increased rather than decreased competition that led to the plaintiff's injury. *SmithKline Beecham Corp. v. Apotex Corp.*, 383 F. Supp. 2d 686 (E.D. Pa. 2004).

210 See, e.g., *Andrx Pharm., Inc. v. Biovail Corp.*, 256 F.3d 799, 819 (D.C. Cir. 2001) ("The Agreement is not unlike a final, private settlement agreement resolving the patent infringement litigation by substituting a market allocation agreement. Such a settlement agreement would not enjoy *Noerr-Pennington* immunity and neither does the Agreement here."); *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 618, 641 (E.D. Mich. 2000) ("When parties petition a Court for judicial action, protection attaches, but when they voluntarily withdraw their disputes from the court and resolve it by agreement among themselves there would be no purpose served by affording *Noerr-Pennington* protection. The parties by doing so must abide with any antitrust consequences that result from their settlement.").

211 See, e.g., *Schor v. Abbott Labs*, 457 F.3d 608 (7th Cir. 2006).

212 See *Teva Pharmaceuticals USA, Inc. v. Pfizer Inc.*, 395 F.3d 1324, (Fed. Cir. 2005); *Merck & Co., Inc. v. Apotex, Inc.*, 488 F. Supp. 2d 418 (D. Del. 2007) (holding that Merck's giving and Apotex's acceptance of a covenant not to sue settling patent infringement litigation denied the court jurisdiction over the claim and was thus not a triggering event setting the clock running so that Apotex could enter the market). On appeal, the *Merck* case was dismissed as moot.

213 *Merck*, *supra* (citing 149 Cong. Rec. S15885 (Nov. 25, 2003) (remarks of Sen. Kennedy, ranking member of Senate HELP committee)).

214 549 U.S. 118 (2007).

215 *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278 (Fed. Cir. 2008); *Dey Pharma, LP v. Sunovion Pharms., Inc.*, 677 F.3d 1158 (Fed. Cir. 2012). Compare *Janssen Pharm., N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1357-58 (Fed. Cir. 2008) (no declaratory judgment jurisdiction to invalidate one listed patent where generic had already stipulated that it infringed another valid, later-expiring patent, so that even invalidating the first patent would not have permitted it to enter the market).

215.1 595 F.3d 1303 (D.C. Cir. 2010).

215.2 2012 WL 1388256 (D.D.C. Apr. 23, 2012).

216 See *E.R.R. Presidents Conference v. Noerr Motor Freight, Inc.,* 365 U.S. 127, 140-41 (1961) (rejecting evidence that the defendants used misinformation and deceptive propaganda in an antitrust suit based on petitioning). For a discussion of the problems this causes for regulatory agencies facing misrepresentations, see Lars Noah, Sham Petitioning as a Threat to the Integrity of the Regulatory Process, 74 N.C. L. Rev. 1 (1995).

217 See *BE&K Constr. Co. v. NLRB*, 536 U.S. 516, 525-26 (2002) ("[W]hile genuine petitioning is immune from antitrust liability, sham petitioning is not.").

218 138 F.T.C. 1, 5 (2004).

219 *Id.* at 5-7.

220 *Id.* at 5-8.

221 *Id.* at 5-7.

222 *Id.* at 7, 12.

223 *Id.* at 10-11. The complaint also alleges that Unocal tweaked its patent applications during prosecution to more closely match the emerging state standard. *Id.* at 10. Unocal ultimately settled private suits based on the same conduct for $48 million. Erin Marie Daly, Chevron to Pay $48M in Calif. Unocal Patent Suit, Law 360, Aug. 11, 2008, http://competition.law360.com/print_article/65699.

224 *Id.* at 8.

225 *United States v. Grinnell Corp.,* 384 U.S. 563, 570-71 (1966).

226 *Rambus Inc. v. FTC*, 522 F.3d 456, 459 (D.C. Cir. 2008); *Broadcom Corp. v. Qualcomm Inc.,* 501 F.3d 297, 303 (3d Cir. 2007).

227 See §35.5b.

228 *NYNEX Corp. v. Discon, Inc.*, 525 U.S. 128, 131-32 (1998).

229 *Id.*

230 *Id.* at 136-37.

231 See *id.* at 135 ("[T]he specific legal question before us is whether an antitrust court considering an agreement by a buyer to purchase goods or services from one supplier rather than another should (after examining the buyer's reasons or justifications) apply the *per se* rule if it finds no legitimate business reason for that purchasing decision.").

232 *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus.*, 508 U.S. 49, 56 (1993).

233 See *United Mine Workers v. Pennington*, 381 U.S. 657, 669-71 (1965) (invoking the principle to allow the petitioning of Executive Branch officials and administrative agencies); *E. R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 136, 140-41 (1961) (barring an antitrust claim against a railroad consortium based on a misleading publicity campaign that was aimed to influence legislation).

234 The *Noerr* Court explained:

> In a representative democracy such as this, these branches of government act on behalf of the people and, to a very large extent, the whole concept of representation depends upon the ability of the people to make their wishes known to their representatives. To hold that the government retains the power to act in this representative capacity and yet hold, at the same time, that the people cannot freely inform the government of their wishes would impute to the Sherman Act a purpose to regulate, not business activity, but political activity, a purpose which would have no basis whatever in the legislative history of that Act.

365 U.S. at 137.

235 See *id.* at 138 ("The right of petition is one of the freedoms protected by the Bill of Rights, and we cannot, of course, lightly impute to Congress an intent to invade these freedoms.").

236 *Id.* at 137; see *id.* at 140-41 ("Insofar as [the Sherman] Act sets up a code of ethics at all, it is a code that condemns trade restraints, not political activity, and…a publicity campaign to influence governmental action falls clearly into the category of political activity.").

237 *Id.* at 144.

238 See, e.g., *Cal. Motor Transp. Co. v. Trucking Unlimited,* 404 U.S. 508, 512 (1972) (finding no *Noerr-Pennington* immunity where defendants "sought to bar their competitors from meaningful access to adjudicatory tribunals and so to usurp that decisionmaking process" by initiating actions "with or without probable cause, and regardless of the merits of the cases").

239 *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.,* 382 U.S. 172, 177 (1965) ("Walker's counterclaim alleged that Food Machinery obtained the patent by knowingly and willingly misrepresenting facts to the Patent Office. Proof of this assertion would be sufficient to strip Food Machinery of its exemption from the antitrust laws.").

240 For a thorough analysis of *Noerr-Pennington* immunity in the context of agency misrepresentations, see the FTC's decision in *Unocal*. *Union Oil Co. of Cal.,* 138 F.T.C. 1 (2004). We generally agree with the FTC's view that *Noerr-Pennington* immunity does not apply to “deliberate misrepresentations that substantially affect the outcome of a proceeding or so infect its core to deprive the proceeding of legitimacy.” *Id.* at 29.

241 See *id.* at 46 (“Clearly, a proceeding fundamentally tainted by misrepresentation lacks the ‘genuine’ nature that is the hallmark of what the Supreme Court seeks to protect.”).

242 *Id.* at 29; see also Herbert Hovenkamp, Federalism and Antitrust Reform, 40 U.S.F. L. Rev. 627, 633, 632-33 (2006) (“[A]ntitrust need not countenance restraints in which the effective decision makers are the market participants themselves.”).

243 The lawsuit would presumably proceed under 35 U.S.C. § 271(e), as the generic has not yet begun making, using, or selling the product and therefore does not violate § 271(a).

244 21 C.F.R. § 314.107(b)(3).

245 See *Andrx Pharmaceuticals v. Biovail Corp. Int'l.*, 276 F.3d 1368 (Fed. Cir. 2002).

246 *Id.* at 1378.

247 *Apotex, Inc. v. Thompson*, 347 F.3d 1335 (Fed. Cir. 2003) (statute permits FDA to treat Orange Book listing as a purely ministerial act; there is no right to “de-listing” of patents in the Orange Book); *aaiPharma, Inc. v. Thompson*, 296 F.3d 227 (4th Cir. 2002) (FDA has no obligation to police Orange Book listings); *Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323, 1328-1333 (Fed. Cir. 2001). In *Mylan*, a generic drug applicant

sought to delist a patent from the Orange Book. *Id.* at 1325. The court denied the request, however, finding no such cause of action exists "outside a properly filed patent case." *Id.* at 1331-1333.

248 21 U.S.C. § 355(j)(5)(b).

248.1 132 S. Ct. 1670 (2012).

248.2 601 F.3d 1359, 1368 (Fed. Cir. 2010) (Dyk, J., dissenting).

248.3 132 S. Ct. at 1678.

249 185 F. Supp. 2d 363 (S.D.N.Y. 2002).

250 *Id. at 369-370* ; see also *Abraxis Bioscience v. Navinta LLC*, 2008 WL 2967034 (D.N.J. July 31, 2008) (bifurcating and staying but allowing to survive *Noerr* scrutiny antitrust claim based on pharmaceutical patent owner improperly delaying the listing of patents in the Orange Book in order to delay ANDA approval). Cf. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188 (E.D.N.Y. 2003) (rejecting *Noerr* immunity where private settling parties requested the district court to enter their settlement as a judgment; the court's decision was merely ministerial).

251 See 1 Antitrust Law ¶210.

252 *Buspirone*, 185 F. Supp. 2d at 371.

253 *Watson Pharm., Inc. v. Henney*, 192 F. Supp. 2d 442, 445 (D. Md. 2001) ; accord *Mylan Pharm., Inc. v. Thompson*, 139 F. Supp. 2d 1, 10-11 (D.D.C. 2001) (FDA's role in listing patents is purely ministerial), rev'd on other grounds, 268 F.3d 1323 (Fed. Cir. 2001).

254 2003 WL 21196817 (E.D.N.Y. May 15, 2003). See also Christine S. Paine, Brand-Name Drug Manufacturers Risk Antitrust Violations by Slowing Generic Production Through Patent Layering, 33 Seton Hall. L. Rev. 479, 507 (2002) (noting that seeking patents from the PTO will be protected under *Noerr*, even if part of an anticompetitive strategy).

255 335 F. Supp. 2d 522 (D.N.J. 2004).

256 540 U.S. 398 (2004).

257 See 21 C.F.R. § 314.53(f).

258 335 F. Supp. 2d at 531.

259 On *Walker Process* claims, see § 11.2.

260 *Buspirone*, *supra* (quoting *Walker Process*, 382 U.S. at 177).

260.1 2009 WL 2751029 (D.N.J. Aug. 28, 2009).

261 See *Astra AG v. Kremers Urban Dev. Co.*, No. 99 Civ. 8928 (BSJ) (S.D.N.Y. Oct. 26, 2001) (dismissing a patent misuse allegation based on improper listing of a patent in the FDA's Orange Book, but sustaining a misuse theory based on a "false" Paragraph IV certification).

262 157 F.3d 1340 (Fed. Cir. 1998)

263 *Ranbaxy Laboratories Ltd. v. Leavitt*, 469 F.3d 120 (D.C. Cir. 2006) (striking down FDA regulation making manufacturer of generic drug ineligible for 180 days of market exclusivity if the holder of the new drug application seeks to delist the patent rather than to litigate validity or infringement). Similarly, in *Teva Pharms. v. Sebelius*, 595 F.3d 1303 (D.C. Cir. 2010). the FDA ruled that Teva was not entitled to exclusivity in that circumstance. The D.C. Circuit reversed that conclusion as arbitrary and capricious. While the statute provided for forfeiture of generic exclusivity in a variety of circumstances, it made no sense to impose forfeiture here.

263.1 Michael A. Carrier & Daryl Wander, Citizen Petitions: An Empirical Study, 34 Cardozo L. Rev. (2012) (petitions against generics increased 68%; more than ¾ of brand petitions challenge generic drugs).

263.2 21 U.S.C. § 355(q).

263.3 *Id.* § 355(q)(1)(A). The provision does not apply to citizen petitions directed at 180-day generic exclusivity, however. *Id*. § 355(q)(4).

264 See *In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677, 694 (2d Cir. 2009) (holding that *Noerr* applies to citizen petitions, but finding that the petition at issue was a sham); *Aventis Pharma S.A. v. Amphastar Pharmaceuticals, Inc.*, 5:03-cv-00887 (C.D. Cal. Feb. 17, 2009) (*Noerr* defeats non-sham citizen petition claim); *In re Wellbutrin XL Antitrust Litig.*, 2012 WL 1657734 (E.D. Pa. May 11, 2012) (*Noerr* applies to citizen petition claims; finding some but not all petitions to be shams).

265 2008 WL 169362 (S.D.N.Y. Jan. 18, 2008).

266 *Louisiana Wholesale Drug Co., Inc. v. Sanofi-Aventis*, 2008 WL 4580016, 2008-2 Trade Cases ¶76,339 (S.D.N.Y. Oct. 14, 2008).

266.1 *Louisiana Wholesale Drug Co., Inc. v. Sanofi-Aventis*, 2009 WL 2708110 (S.D.N.Y. Aug. 28, 2009).

266.2 *In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677, 694 (2d Cir. 2009); *In re Flonase Antitrust Litig.*, 795 F. Supp. 2d 300 (E.D. Pa. 2011); *In re Prograf Antitrust Litig.*, 2012 WL 293850 (D. Mass. Feb. 1, 2012).

266.2.1 Reckitt Benckiser, Docket No. FDA-2012-P-1028 (FDA Feb. 22, 2013). Reckitt Benckiser's actions look like a classic form of product hopping, discussed in § 15.3c1.

266.3 *Andrx Pharms., Inc. v. Biovail Corp., Inc.*, 256 F.3d 799, 806 (D.C. Cir. 2001).

266.4 Thus, in *In re Wellbutrin XL Antitrust Litig.*, 2012 WL 1657734 (E.D. Pa. May 11, 2012), the court found that some—but not all—of the citizen petitions filed by Biovail were shams. It concluded that the fact that some petitions were successful did not immunize Biovail from liability for the sham petitions, but that fact did create causation issues. Because the plaintiffs could not show that generic entry was delayed because of the sham petitions more than it had already been delayed by the non-sham petitions, it found no antitrust harm from the sham petitioning.

266.5 *In re Prograf Antitrust Litig.*, 2012 WL 293850 (D. Mass. Feb. 1, 2012).

266.6 *Andrx*, 256 F.3d at 807; *Xechem Inc. v. Bristol-Myers Squibb Co.*, 372 F.3d 899, 902 (7th Cir. 2004); *Roxane Labs. v. SmithKline Beecham Corp.*, 2010 WL 331704 (E.D. Pa. Jan. 26, 2010); *In re Metoprolol Succinate Direct Purchaser Antitrust Litig.*, 2010 WL 1485328 (D. Del. Apr. 13, 2010). *Metoprolol* went so far as to hold that even a petition that is not approved at all during the 30-month stay can support antitrust standing, since "generic manufacturers may divert resources from FDA approval to patent litigation—resulting in a delay in receiving tentative approval." *Id.* (quoting *In re Wellbutrin SR/Zyban Antitrust Litig.*, 281 F. Supp. 2d 751, 757 (E.D. Pa. 2003)).

In a curious inversion of the issue, in *AstraZeneca Pharms. LP v. FDA*, 2012 WL 983481 (D.D.C. Mar. 23, 2012), the brand owner filed a petition with the FDA seeking an advance determination that it would be entitled to a "new patient population" exclusivity period after its existing exclusivity expired and that ANDA applications should not be approved until the end of that period. The FDA denied the petitions as premature, since it had not made a final determination on any ANDA application. AstraZeneca sought a preliminary injunction requiring the FDA to block any ANDA petitions. The district court denied the injunction as unripe because there were no ANDAs yet approved by the FDA.

267 21 U.S.C. § 355(b)(1) (2008). The Orange Book (officially titled Approved Drug Products with Therapeutic Equivalence Evaluations but nicknamed for the color of its cover) provides a comprehensive listing of all drugs approved by the FDA. See Electronic Orange Book, http:// www.fda.gov/cder/ob.

268 Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act, Pub. L. No. 98-417, § 101, 98 Stat. 1585, 1585-92 (1984) (codified at 21 U.S.C. § 355(j)(5)(A)) (requiring that the approval process be completed within 180 days of the filing of the application). From animal testing and clinical trials, through full FDA approval, the process for new-drug approval can take up to ten years. Judy Vale, Note, Expanding Expanded Access: How the Food and Drug Administration Can Achieve Better Access to Experimental Drugs for Seriously Ill Patients, 96 Geo. L.J. 2143, 2169 n.212 (2008).

269 21 U.S.C. § 355(j)(2)(A)(iv). Because they lacked the resources to perform clinical trials, small generic-drug makers found it difficult to meet the pre-Hatch-Waxman safety and efficacy requirements. David A. Balto, Pharmaceutical Patent Settlements: The Antitrust Risks, 55 Food & Drug L.J. 321, 325 (2000). Thus, very few generics were available even for drugs whose patents had expired. *Id.* The Hatch-Waxman Act improved things considerably, leading to a 150 percent increase in the market share of generics between 1984 and 1998. Cong. Budget Office, How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry 1 (1998), available at http://www.cbo.gov/ftpdocs/6xx/doc655/pharm.pdf.

270 21 U.S.C. § 355(j)(5)(A).

271 See Office of Inspector Gen., Dep't of Health & Human Servs., The Food and Drug Administration's Generic Drug Review Process 13 (2008), available at http://www.oig.hhs.gov/oei/reports/oei-04-07-00280.pdf (noting that the FDA review process for ANDAs often exceeds the 180-day statutory maximum).

272 As a general matter, state laws authorize such substitutions, and payers (such as insurance companies, HMOs, and government agencies) decide whether to allow or mandate substitutions for their covered patients. As the price of branded drugs continues to escalate, more and more insurers and other parties require generic substitution when it is available. See Cong. Budget Office, *supra* note 267, at 7 (describing the process by which managed-care plans prevent higher costs by substituting generic drugs on their formularies).

273 In addition to the *Abbott v. Teva* case discussed below, see *FTC v. Warner Chilcott Holdings Co.*, 2006 WL, 3302862 (D.D.C. Oct. 23, 2006).

274 See *Abbott Labs v. Teva Pharm.*, 432 F. Supp. 2d 408, (D. Del. 2006) (citing Treatise).

275 432 F. Supp. 2d 408 (D. Del. 2006). To the extent it is relevant, M.L. represented Impax Labs, antitrust plaintiff in this case.

276 *Id.* at 421.

277 *Id.* at 422 (citing Treatise) (citation omitted).

277.1 Curiously, a district court in Pennsylvania eight years later referred to a very similar product-hopping scheme as “novel at best,” and clearly seemed skeptical that product hopping could be illegal. Nonetheless, the court declined to reject the theory on a motion to dismiss. *Mylan Inc. v. Warner Chilcott Co.*, No. 2:12-cv-03824-PD (E.D. Pa. June 12, 2013).

278 *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 191 (3d Cir. 2005).

279 *Microsoft,* 253 F.3d at 64.

280 432 F. Supp. 2d 408, 423.

281 534 F. Supp. 2d 146 (D.D.C. 2008).

282 *Id.* at 152.

283 *Id.* at 151.

284 In *Apotex, Inc. v. Thompson*, 347 F.3d 1335 (Fed. Cir. 2003), for example, the drug manufacturer had originally named a single patent in its Orange Book listing for a pioneer drug. In response to a generic's ANDA and Paragraph IV certification, the manufacturer sued for patent infringement, thus triggering an initial thirty-month stay. *Id.* at 1339. While that lawsuit was pending, the manufacturer obtained additional patents, which it added to its Orange Book listing and used as the basis for yet another lawsuit and stay. *Id.* Remarkably, while that lawsuit was pending, the firm listed three additional patents in its Orange Book listing for the same drug, thereby triggering yet another round of notice, lawsuit, and thirty-month stay. *Id.* at 1340; see also *In re Buspirone Patent Litig.*, 185 F. Supp. 2d 363 (S.D.N.Y. 2002) (describing Bristol-Myers's strategic filing of patent-infringement suits to trigger automatic stays of the FDA's approval of competing generic products). This tactic is typically referred to as “evergreening.” Mark A. Lemley &

Kimberly A. Moore, Ending Abuse of Patent Continuations, 84 B.U. L. Rev. 63, 81-83 (2004). Congress passed legislation in 2003 to eliminate this particular form of patent evergreening. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1101(a)(2)(A)(ii), 117 Stat. 2066, 2449-50 (codified at 21 U.S.C. § 355(j)(5)(B)(iii)). The new law limits patentees to a single, thirty-month stay for any given drug, regardless of how many patents it may list in the Orange Book.

284.1 Michael Carrier has argued that delayed-entry settlements can compound the problem of product-hopping, because a settlement that delays entry (whether or not conditioned on an exclusion payment) can give the patent owner time to engage in a product hop and therefore further delay entry. Michael A. Carrier, A Real-World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product-Hopping, 62 Fla. L. Rev. 1009 (2010). Carrier's factual point makes sense, though it might be one generic companies could contract to avoid. If they don't, or can't, antitrust law is capable of considering the overall course of conduct. Nonetheless, we think the settlement itself would not generally be anticompetitive without the added element of product-hopping.

285 See Guy V. Amoresano, Branded Drug Reformulation: The Next Brand vs. Generic Antitrust Battleground, 62 Food & Drug L.J. 249, 256 (2007) ("It may be that a more appropriate approach…to leave it to FDA and the state legislatures to determine if some modification of FDA 'AB rating' guidelines and state [Drug Product Selection] Laws is prudent to address scenarios in which inconsequential reformulations affect the speed of generic drug market entry."). Such an approach would raise challenges of its own, such as how to treat substitutions between products with the same active ingredients but different dosages.

286 See *United States v. Grinnell Corp.,* 384 U.S. 563, 571 (1966) (condemning behavior that "was done plainly and explicitly for a single purpose" of driving out competitors); see also *United States v. Microsoft Corp.,* 253 F.3d 34, 65 (2001) ("Judicial deference to product innovation…does not mean that a monopolist's product design decisions are per se lawful.").

287 See, e.g., *Microsoft*, 253 F.3d at 65-67 (balancing the anticompetitive effect of design choices against the business justifications offered by the defendant); *C. R. Bard Co. v. M3 Sys.,* 157 F.3d 1340, 1382 (Fed. Cir. 1998) (Bryson, J., delivering the opinion of the court on this issue, concurring in part and dissenting in part on other issues) (finding liability for a product-design change that did not improve the product, but merely excluded competing, complementary products).

288 *Abbott Labs. v. Teva Pharm. USA, Inc.,* 432 F. Supp. 2d 408, 422 (D. Del. 2006) (citing *Microsoft*, 253 F.3d at 59, 66-67).

289 See *id.* (holding that plaintiffs need not prove the new formulations are "absolutely no better than the prior version" or intended to eliminate a rival's complementary product, but "[r]ather, as in *Microsoft*, if Plaintiffs show anticompetitive harm from the formulation changes, that harm will be weighed against any benefits presented by Defendants").

290 *Id.* at 423, 422-23.

291 *Id.* at 422.

292 *Id.* (quoting *Microsoft*, 253 F.3d at 59). See generally Kolasky, *supra* note 60, at 88-89 (suggesting a "sliding scale" framework for weighing procompetitive and anticompetitive effects in rule-of-reason cases).

293 See *supra* §12.3.

294 See generally 3B Antitrust Law ¶767c, at 137-43; ABA Section of Antitrust Law, Energy Antitrust Handbook: A Guide to the Electric and Gas Industries 121-25 (2002) (discussing price-squeeze cases). Judge Learned Hand first recognized price squeezes as an antitrust violation in *United States v. Aluminum Co. of Am.,* 148 F.2d 416, 437-38 (2d Cir. 1945).

295 *Pac. Bell Tel. Co. v. linkLine Commc'ns, Inc.,* 555 U.S. __, 129 S. Ct. 1109 (2009).

296 *linkLine Commc'ns, Inc. v. SBC Cal., Inc.,* 503 F.3d 876, 879 (9th Cir. 2007), rev'd, 555 U.S. at __, 129 S. Ct. 1109 (2008).

297 See, e.g., J. Gregory Sidak, Abolishing the Price Squeeze as a Theory of Antitrust Liability, 4 J. Competition L. & Econ. 279, 298 (2008). Sidak argues:

> If an unregulated, vertically integrated firm truly is a monopolist in the supply of the bottleneck input, and if downstream competitors use that input in fixed proportion to their production of the retail product, then the "one monopoly profit theory" implies that the vertically integrated firm has no incentive to attempt the price squeeze.

Id. The one-monopoly-profit theory has led to a general skepticism about applying antitrust law to vertical restraints. As described by Judge Posner:

> Imagine an industry with two levels, production and distribution: if production is monopolized and distribution is competitive, can the monopolist increase his profits by buying out the distributors?…If the producer acquires the distributors and increases the retail markup he will have to decrease the producer markup by the same amount. He cannot maximize his profits by charging a price above the monopoly price ….

Richard A. Posner, Antitrust Law: An Economic Perspective 197 (1976); see also Phillip E. Areeda & Louis Kaplow, Antitrust Analysis 489 (5th ed. 1997) ("The power already possessed by the…monopolist to control the price and output…effectively controls the price and output of the independent [downstream firms]."); Robert H. Bork, The Antitrust Paradox: A Policy at War with Itself 229 (1993) ("[A] monopolist has no incentive to gain a second monopoly that is vertically related to the first, because there is no additional monopoly profit to be taken."); *cf. G.K.A. Beverage Corp. v. Honickman*, 55 F.3d 762, 767 (2d Cir. 1995) ("[A] vertically structured monopoly can take only one monopoly profit."); Charles F. Rule, Patent-Antitrust Policy: Looking Back and Ahead, 59 Antitrust L.J. 729, 731 (1991) ("[T]here is only a single monopoly price for any given product, and you can either sell that product alone or you can combine it with as many complements as you want, but you are only going to be able to earn that one monopoly profit.").

298 See, e.g., Pietro Crocioni, Leveraging of Market Power in Emerging Markets: A Review of Cases, Literature, and a Suggested Framework, 4 J. Competition L. & Econ. 449, 458-69 (2008) (summarizing the arguments for and against the one-monopoly-profit theory); Joseph Farrell & Philip J. Weiser, Modularity, Vertical Integration and Open Access Policies: Towards a Convergence of Antitrust and Regulation in the Internet Age, 17 Harv. J.L. & Tech. 85, 105-19 (2003) (listing exceptions to the one-monopoly-rent theorem); *cf. Town of Concord v. Boston Edison Co*., 915 F.2d 17, 25-29 (1st Cir. 1990) (laying out the economic arguments for and against price squeezes); Roger D. Blair & David L. Kaserman, Law and Economics of Vertical Integration and Control 124-35 (1983) (outlining the advantages and disadvantages, for an upstream monopolist, of vertical integration as a method to achieve a long-run, competitive equilibrium downstream); Statement, FTC, Declining to Join a Petition for a Writ of Certiorari in *Pacific Tel. Co. d/b/a AT&T California v. linkLine Commc'ns, Inc.* (No. 07-512) (May 23, 2008), available at http://www.ftc.gov/os/2008/05/P072104stmt.pdf (highlighting two of the arguments made in *Town of Concord*).

299 Not all commentators view even predatory price squeezes as problematic. See, e.g., Sidak, *supra* note 294, at 282, 282-84 ("If a vertically integrated monopolist willing to provide inputs to rivals at a negotiated price exposes itself to a potential price-squeeze claim when it lowers its retail prices, it faces a strong disincentive to deal at all.").

300 See, e.g., *Covad Commc'ns Co. v. Bell Atl. Co.*, 407 F.3d 1220, 1222 (D.C. Cir. 2005) (suggesting that a price-squeeze claim may lie if a plaintiff alleges predatory pricing at the retail level); *Covad Commc'ns Co. v. BellSouth Corp.*, 374 F.3d 1044, 1050 (11th Cir. 2004) (holding that the plaintiff's price-squeeze claim was "based on traditional antitrust doctrine" and "[a]s such…must contain allegations that the two basic prerequisites for a showing of price predation under § 2 of the Sherman Act have been met").

301 As discussed above, antitrust courts should not ordinarily second-guess decisions affirmatively made by regulators within their core areas of expertise. For fully regulated industries, the fact that the regulator has specifically approved both levels of prices counsels against antitrust intervention.

302 *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 222-23 (1993).

303 See Herbert J. Hovenkamp & Erik N. Hovenkamp, The Viability of Antitrust Price Squeeze Claims, 51 Ariz. L. Rev. 273 (2009) (making this argument). Justice Breyer's concurring opinion in *Linkline* showed some sympathy for this type of claim. See *Pac. Bell Tel. Co. v. linkLine Commc'ns, Inc.*, 555 U.S. __, 129 S. Ct. 1109 (2009) (Breyer, J., concurring) (concluding that price squeezes may violate the antitrust laws when they "involve a 'course of dealing' that, even if profitable, indicates a 'willingness to forsake short-term profits to achieve an anticompetitive end'").

304 *linkLine Commc'ns, Inc. v. SBC Cal., Inc.*, 503 F.3d 876, 878 (9th Cir. 2007),

305 *Id.* at 879.

306 *Id.* at 880; see *id.* at 885.

307 *Pac. Bell Tel. Co. v. linkLine Commc'ns, Inc.*, 555 U.S. __, 129 S. Ct. 1109, 1119 (2009) (" *Trinko* thus makes clear that if a firm has no antitrust duty to deal with its competitors at wholesale, it certainly has no duty to deal under terms and conditions that the rivals find commercially advantageous."). The district court had concluded that Pacific Bell had no antitrust duty to deal, and the Court both acknowledged and endorsed that conclusion. See *id.* at 1118 ("noting that "the District Court held that AT&T had no such antitrust duty to deal with its competitors,…and this holding was not challenged on appeal"); *id.* & n.2 ("Even aside from the District Court's reasoning,…it seems quite unlikely that AT&T would have an antitrust duty to deal with the plaintiffs. Such a duty requires a showing of monopoly power, but…the market for high-speed Internet service is now quite competitive.…").

308 *Id.* at 1120.

309 "'[M]eans of illicit exclusion,'" Justice Breyer declares, "may involve a 'course of dealing' that, even if profitable, indicates a 'willingness to forsake short-term profits to achieve an anticompetitive end.'" He continues:

> And, as Judge Hand wrote many years ago, a 'price squeeze' may fall into the latter category.… As a matter of logic, it may be that a particular price squeeze can only be exclusionary if a refusal by the monopolist to sell to the 'squeezed customer' would also be exclusionary. But a court, faced with a price squeeze rather than a refusal to deal, is unlikely to find the latter (hypothetical) question any easier than the former."

Id. at 1124.

310 *Id.* (citing *Town of Concord v. Boston Edison Co.*, 915 F.2d 17, 26-29 (1st Cir. 1990)).

311 Indeed, this is the main justification for vertical integration more generally: it often costs less to integrate different operational layers into a single enterprise.

312 *Cf. BellSouth Corp.*, 374 F.3d at 1051 (holding that the relationship between wholesale and retail prices "is a factual matter for the district court to determine at a later stage in the proceedings").

313 457 F.3d 608 (7th Cir. 2006).

314 *Id.* at 614.

315 *In re Abbott Labs Norvir Anti-Trust Litig.*, 442 F. Supp. 2d 800 (N.D. Cal. 2006).

316 See *Image Tech. Servs. v. Eastman Kodak Co.*, 125 F.3d 1195 (9th Cir. 1997).

317 *Doe v. Abbott Labs*, 571 F.3d 930 (9th Cir. 2009) (quoting *Pacific Bell Telephone Co. v. linkLine Communications, Inc.*, 129 S. Ct. 1109 (2009)).

318 *Id.*

319 *Id.*

320 2010 WL 147988 (N.D. Cal. Jan. 12, 2010).

321 515 F.3d 883, 910 n.21 (9th Cir. 2008).